D. D. N. J., F. D. C. 326–425

Issued March 1942

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

326–425

DRUGS AND DEVICES

The cases reported herewith, commenced prior to June 30, 1940, were instituted in the United States District Courts by the United States attorneys acting upon reports submitted by direction of the Secretary of Agriculture; and those commenced on and after that date were similarly instituted upon reports submitted by direction of the Federal Security Administrator.

PAUL V. MCNUTT, *Administrator, Federal Security Agency.*

Washington, D. C., January 15, 1942.

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326. Misbranding of Pachanga Mineral Water. U. S. v. Tripo M. Lukovich, trading as T. M. Lukovich, D. C. Plea of guilty. Fine of $100 on count I. Imposition of sentence suspended on count II and defendant placed on probation for 2 years. (F. D. C. No. 2956. Sample Nos. 31518–E, 31532–E.)

This product contained excessive fluorine and would be dangerous to health when used as directed in the labeling. Its labeling failed to reveal the fact that it contained fluorine and failed to bear adequate warnings against use by children. The labeling of one lot contained false and misleading representations regarding its efficacy in certain ailments and conditions and failed to bear an accurate statement of the quantity of the contents.

On April 24, 1941, the United States attorney for the Southern District of California filed an information against Tripo M. Lukovich, trading as Dr. T. M. Lukovich, D. C., Elsinore, Calif., alleging shipment on or about September 5 and November 25, 1940, from the State of California into the State of Michigan of quantities of Pachanga Mineral Water that was misbranded.

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Analysis showed that the article consisted essentially of sodium chloride, sodium sulfate, sodium bicarbonate, sodium carbonate, a fluorine compound, and a trace of an iron compound, dissolved in water. The total amount of dissolved matter was 2 percent. Samples taken from the two shipments were found to contain 52.2 and 60 parts, respectively, per million of fluorine.

The product in both shipments was alleged to be misbranded in that it would be dangerous to health when used in the dosage or with the frequency prescribed, recommended, and suggested in the labeling, namely, (one shipment) "Directions: From ½ to ¾ of an ordinary glass before breakfast and before retiring"; (second shipment) "Natural Water," since it contained an excessive amount of fluorine.

Both lots were alleged to be misbranded further in that the labeling was misleading since it failed to reveal the fact that the article contained fluorine, a poisonous substance, which fact is material in the light of the representations made in the labeling and material with respect to consequences which might result from the use of the article under the conditions of use prescribed in the labeling and under such conditions of use as are customary or usual.

Both lots were alleged to be misbranded further in that the labeling did not bear adequate warnings against use by children, where its use might be dangerous to health or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users. The shipment of September 5, 1940, was alleged to be misbranded further in that the following statements in the labeling, "Try Pachanga Water for the Relief of certain ailments of Stomach, Bowels, Liver, Kidney, etc." and "Chemical Analysis show that Pachanga Water contains many mineral ingredients in a combination which has proven remarkably beneficial for many ailments of the human system," borne on the bottle label, were false and misleading since the article would not be efficacious and beneficial in the treatment of such ailments. This shipment was alleged to be misbranded further in that the bottle label failed to bear an accurate statement of the quantity of the contents.

On May 26, 1941, a plea of guilty having been entered, the court imposed a fine of $100 on count I and ordered that imposition of sentence be suspended on count II and that the defendant be placed on probation for 2 years.

327. Misbranding of Pachanga Mineral Water. U. S. v. 59 Bottles of Pachanga Mineral Water. Default decree of condemnation and destruction. (F. D. C. No. 3568. Sample No. 31532–E.)

This product contained fluorine. It would be dangerous to health when used as directed in the labeling, and it was not labeled to indicate the consequences that might result from its use.

On December 21, 1940, the United States attorney for the Eastern District of Michigan filed a libel against 59 bottles of Pachanga Mineral Water at Detroit, Mich., alleging that the article had been shipped in interstate commerce on or about November 25, 1940, by Dr. T. M. Lukovich from Elsinore, Calif.: and charging that it was misbranded. It was labeled in part: "Pachanga Mineral-Antiacid-Laxative Natural Water Pachanga Mineral Well."

The article was alleged to be misbranded in that the statement "Mineral-Antiacid-Laxative Natural Water" was false and misleading since the label failed to reveal the fact that the article contained fluorine, a poisonous substance.

It was alleged to be misbranded further in that the label failed to bear adequate warnings against use by children where its use might be dangerous to health and against unsafe dosage and methods and duration of administration in such manner and form as are necessary for the protection of users.

It was alleged to be misbranded further in that it was dangerous to health when used in the dosage or with the frequency or duration suggested in the labeling "Natural Water."

On January 9, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

328. Misbranding of Aspirol Tablets and headache tablets. U. S. v. 1,005 Bottles of Aspirol Tablets and 1,416 Bottles of Headache Tablets. Consent decree of condemnation. Aspirol Tablets ordered released under bond for relabeling; headache tablets ordered destroyed. (F. D. C. Nos. 2222, 2223. Sample Nos. 15165–E, 15169–E.)

The product Aspirol Tablets was labeled to indicate that it was an aspirin preparation; whereas it contained other physiologically active ingredients. Its label also failed to bear a statement of the quantity of acetophenetidin that it

contained. The headache tablets contained acetanilid and would be dangerous to health when used as directed, and the label failed to reveal the consequences which might result from their use.

On June 17, 1940, the United States attorney for the Southern District of Illinois filed a libel against 1,005 bottles of Aspirol Tablets and 1,416 bottles of headache tablets at Bloomington, Ill., alleging that the articles had been shipped in interstate commerce on or about July 3, 1939, and April 19, 1940, by the J. R. Watkins Co. from Winona, Minn.; and charging that they were misbranded.

The Aspirol Tablets were alleged to be misbranded in that the name was false and misleading because it was derived from the ingredient aspirin; whereas they contained other active ingredients, including acetophenetidin and caffeine citrate. They were alleged to be misbranded further in that they were fabricated from two or more ingredients and the label failed to bear a statement of the quantity of acetophenetidin contained in each tablet.

The Headache Tablets were alleged to be misbranded in that the statements in the labeling, "Headache * * * If pain is severe take two tablets for first dose * * * Directions: Adults: One tablet every 2 hours until relieved. Take no more than 4 tablets in 24 hours. Children: Over 10 (only) half dose," were false and misleading since they created the impression that the article constituted an appropriate treatment for headache; whereas it was not such a safe and appropriate remedy but was a dangerous drug, and the label failed to reveal the fact, material in the light of the representations made as quoted hereinbefore, that the use of the article in accordance with the directions might cause serious blood disturbances, anemia, collapse, or a dependence on the drug. It was alleged to be misbranded further in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling.

On February 25, 1941, G. C. Heberling Bros., Bloomington, Ill., having appeared as claimant and having consented to the entry of a decree, judgment of condemnation was entered and it was ordered that the Aspirol Tablets be released under bond conditioned that they be properly relabeled under the supervision of the Food and Drug Administration and that the headache tablets be destroyed.

329. Misbranding of Watkins Laxative Cold Tablets. U. S. v. 300 Boxes of Laxative Cold Tablets. Default decree of condemnation and destruction. (F. D. C. No. 2310. Sample No. 323–E.)

This product would be dangerous to health when used as directed in the labeling and was not labeled to indicate the consequences that might result from its use. It was misbranded further because it was labeled to indicate that it was a safe and appropriate remedy for the conditions for which it was recommended and in the other respects referred to hereinafter.

On July 6, 1940, the United States attorney for the Western District of North Carolina filed a libel against 300 boxes of laxative cold tablets at Charlotte, N. C., alleging that the article had been shipped in interstate commerce on or about February 15, 1940, by the J. R. Watkins Co., from Newark, N. J.; and charging that it was misbranded.

Analysis showed that the article contained 1.9 grains of acetanilid (1.9 grains per tablet), total alkaloids including quinine and alkaloids of belladonna (0.25 grain per tablet), and extracts of plant drugs including a laxative drug.

The article was alleged to be misbranded in that the following statements (tin container) "Directions * * * For Cold Symptoms. Adult Dose: Take two tablets every three hours until three doses have been taken. This should cause the bowels to move freely. Then take one tablet three times a day until all symptoms are removed. For Casual Headaches. Adult Dose: Two tablets to be followed by one every three hours when necessary (not exceeding 6 in 24 hours). If headaches persist or return frequently, consult your physician. For children. Over ten years of age one-half adult dose; over five years of age one-fourth adult dose," and (circular) "At The First * * * Chill, Or Fever * * * Take Watkins Laxative Cold Tablets * * * Watkins Laxative Cold Tablets contain ingredients that are selected to be used to treat the symptoms of colds and headaches. Especially good for sneezing or nasal discharge, headache and other disagreeable symptoms usually associated with colds. They increase the action of the bowels. In this manner they help to carry off from the system waste substances that tend to keep up the headache

and other discomforts and aid in warding off the effects or in lessening the severity of symptoms. When you find yourself sneezing, chilly and have other symptoms of a cold coming on, do not wait but take early precautions to check their advance and to throw them off before they become severe. The convenience of Watkins Laxative Cold Tablets is something to be appreciated. They are a compound of medicines that have laxative and other properties which assist in overcoming the disagreeable symptoms which are associated with colds. Take as directed and rest as much as possible," and similar directions in various foreign languages, were false and misleading since they created the impression that it constituted an appropriate treatment in these conditions; whereas it was not such a safe and appropriate remedy but was a dangerous drug; and also because the label failed to reveal the fact, material in the light of the representations made as quoted above, that its use in accordance with the directions might cause serious blood disturbances, anemia, collapse, or a dependence on the drug.

It was alleged to be misbranded further in that the statement "Total alkaloids 1/25,000 grain per tablet" and similar statements in foreign languages were false and misleading since the article was found to contain total alkaloids extremely in excess of this amount.

The article was alleged to be misbranded further in that the labeling did not bear adequate directions for use; in that the labeling did not bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods of administration or application, in such manner and form, as were necessary for the protection of users; and in that it was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof as quoted above.

On July 29, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

330. Adulteration and misbranding of One Minute Toothache Stick. U. S. v. 20 Dozen Packages of Toothache Stick. Default decree of destruction. (F. D. C. No. 2159. Sample No. 5305–E.)

This product contained carbolic acid. It would be dangerous to health when used as directed in the labeling and would not be efficacious for certain conditions for which it was recommended in the labeling. It also contained a smaller percentage of carbolic acid than that declared on the label.

On or about June 7, 1940, the United States attorney for the Western District of Kentucky filed a libel against 20 dozen packages of toothache stick at Louisville, Ky., alleging that the article had been shipped in interstate commerce on or about April 12, 1940, by the One Minute Remedies Co. from St. Louis, Mo.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of carbolic acid (23 percent), paraffin, cotton, and small amounts of oils of clove and cinnamon.

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely, 30 percent carbolic acid. It was alleged to be misbranded in that the following statements contained in the accompanying circular were false and misleading, since they purported and represented that it would be efficacious in the conditions named therein: "More than thirty-eight years ago this company determined that the crude and old-fashioned remedy of toothache drops must be abandoned for something better. Drops scald the mouth and gums and lead to sores which may produce serious conditions. After many experiments this Toothache Stick was considered the best; and millions of satisfied users in the last thirty-eight years testify that it stops toothache instantly." It was alleged to be misbranded further in that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling: "Directions: Remove all substances from the tooth, cut a piece of the stick the size required and press firmly into the tooth. Where no cavity exists, press flat and apply as a plaster." It was alleged to be misbranded further in that it was fabricated from two or more ingredients and the label on the bottle did not bear the common or usual name of the active ingredients.

The article was also alleged to be misbranded in violation of the Federal Caustic Poison Act, as reported in notices of judgment published under that act.

On October 15, 1940, no claimant having appeared, judgment was entered ordering that the product be destroyed.

331. Misbranding of radioactive cones. U. S. v. 5 Radioactive Cones. Decree of condemnation with provision for release under bond under certain conditions; otherwise that it be destroyed. Product destroyed. (F. D. C. No. 2530. Sample No. 9585–E.)

This product would be dangerous to health when used in the manner recommended and suggested in the labeling. It also failed to comply with certain labeling requirements of the law as indicated below.

On August 14, 1940, the United States attorney for the Western District of Louisiana filed a libel against 5 radioactive cones at Shreveport, La., alleging that the article had been shipped in interstate commerce on or about March 20, 1940, by the Thomas Radioactive Cone Co. from Inglewood, Calif.; and charging that it was misbranded.

It was alleged to be misbranded in that its labeling was misleading in that it failed to reveal the fact material in the light of the representation that it was radioactive, that when used to impart radioactivity to water the drinking of such water might result in injury to the user; in that its label failed to bear the name and place of business of the manufacturer, packer, or distributor; in that the label failed to bear the common or usual name of the ingredient or ingredients of the article; in that the labeling failed to bear adequate directions for use; in that the labeling failed to bear adequate warnings against use by children and against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users; and in that it was dangerous to health when used with the frequency or duration prescribed, recommended, or suggested in the labeling.

On November 29, 1940, judgment of condemnation was entered and the product was ordered released under bond to Ruby V. Turnley, Longview, Tex., claimant, conditioned that it should not be disposed of in violation of the law. Upon failure of the claimant to comply with the conditions of the decree the product was destroyed.

332. Misbranding of Reed's Effervescent Bromo-Sizz. U. S. v. 83 Display Cartons of Reed's Effervescent Bromo-Sizz. Default decree of condemnation and destruction. (F. D. C. No. 2329. Sample No. 16463–E.)

This product contained acetanilid and would be dangerous to health when used as directed, but was not labeled to show the consequences that might result from its use. The labeling also failed to comply with the law in certain other respects as indicated hereinafter.

On July 10, 1940, the United States attorney for the District of Nebraska filed a libel against 83 display cartons of Reed's Effervescent Bromo-Sizz at Omaha, Nebr., alleging that the article had been shipped in interstate commerce on or about May 17, 1940, by the Reed Products Co. from St. Louis, Mo.; and charging that it was misbranded.

The article was alleged to be misbranded (1) in that it was in package form, and its label failed to bear a statement of the quantity of the contents; (2) its label failed to bear a statement of the quantity or proportion of acetanilid that it contained since the statement "each teaspoonful contains approx. 3 grains acetanilid" was not informative in view of the directions to "add contents of this tube in half glass of water"; (3) its label failed to bear a declaration of the quantity or proportion of sodium bromide present since the statement "sodium bromide approx. 3%" was not a correct statement of the proportion of sodium bromide present and was not informative to the purchaser as to the amount of sodium bromide which would be consumed when the article was taken in accordance with the directions; (4) the label failed to bear adequate directions for use since the directions were incomplete and were not appropriate for an article of the composition found; (5) its label failed to bear adequate warnings against its use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users; and (6) in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely, "Add contents of this tube in half glass of water. Repeat in half hour if necessary. No more than three teaspoonfuls to—" (The words "be taken within 24 hours" which followed the statements quoted were concealed on the package as purchased by overlapping of the label.)

On November 25, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

333. Misbranding of Utra Jel. U. S. v. 32 Tubes of Utra Jel. Default decree of condemnation and destruction. (F. D. C. No. 3196. Sample No. 14082–E.)

This product would be dangerous to health when used as directed in the labeling. It would not be efficacious for certain purposes for which it was recommended. It contained no free iodine as claimed, and the retail carton did not bear the common or usual names of the active ingredients.

On October 14, 1940, the United States attorney for the Eastern District of Pennsylvania filed a libel against 32 tubes of Utra Jel at Philadelphia, Pa., alleging that the article had been shipped in interstate commerce on or about August 15, 1940, by Pynosol Laboratories, Inc., from Chicago, Ill.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of water, soap, pine oil, and combined iodine. It contained no free iodine.

The article was alleged to be misbranded in that the following statement in the labeling was false and misleading since it was not efficacious for the said purposes: "For Specific and Non-Specific Infections of the Cervix and Cervical Canal." It was alleged to be misbranded further in that the following statement appearing in the labeling was false and misleading in that it was incorrect: (Tube) "Active Ingredients: 1% Iodine." It was alleged to be misbranded further in that its carton did not bear the common or usual names of the active ingredients; and in that it was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely: (Carton) "1 to 5cc injected into cervical canal, and about 3–5cc applied on wool tampon to be left in position from 12 to 20 hours"; and (tube) "For Cervical and Intra-Uterine Use."

On November 23, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

334. Misbranding of Young's Preparation. U. S. v. 19 Packages of Young's Preparation. Default decree of condemnation and destruction. (F. D. C. No. 2233. Sample No. 20701–E.)

This product contained acetic acid and would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, which recommended it for the relief of itching skin and scalp and directed that it should be well-shaken and applied to afflicted parts two or three times a day, that if the parts were raw it should be diluted with water until it could be used full strength, and that it was natural for the product to sting when first applied.

On June 25, 1940, the United States attorney for the Southern District of Florida filed a libel against 19 packages of Young's Preparation at Jacksonville, Fla., alleging that the article had been shipped in interstate commerce on or about March 4, 1940, by O. L. Brunson from Waycross, Ga.; and charging that it was misbranded for the reasons appearing above.

It also was alleged to be misbranded in violation of the Federal Caustic Poison Act, as reported in notices of judgment published under that act.

On September 30, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

335. Misbranding of Dr. Young's Rectal Dilators and Dr. Young's Piloment. U. S. v. 67 Sets of Dr. Young's Rectal Dilators and 83 Packages of Dr. Young's Piloment. Default decrees of condemnation and destruction. (F. D. C. Nos. 2490, 2491. Sample Nos. 33914–E, 33915–E.)

The rectal dilator would be dangerous to health when used with the frequency and duration prescribed, recommended, or suggested in the labeling. The labeling of both products bore false and misleading representations regarding their efficacy in the treatment of the conditions indicated below.

On August 7, 1940, the United States attorney for the Southern District of New York filed libels against 67 sets of Dr. Young's Rectal Dilators and 83 packages of Dr. Young's Piloment at New York, N. Y., alleging that the articles had been shipped in interstate commerce within the period from on or about May 10 to on or about June 10, 1940, by F. E. Young & Co. from Chicago, Ill.; and charging that they were misbranded.

Examination of the sets of rectal dilators showed that they consisted of four hard plastic cylinders, flanged at one end, slightly enlarged and pointed at the other end, and varying in diameter from ½ inch to 1 inch and varying in length from 3 to 4 inches. Analysis of the Piloment showed that it consisted essentially of petrolatum (99.15 percent), with phenol (0.73 percent) and extracts of drugs including a mydriatic drug such as belladonna.

The rectal dilator was alleged to be misbranded in that representations in the labeling that it was a simple, harmless, convenient, nonhabit-forming, and ideal treatment to bring satisfactory results and permanently overcome constipation and piles by inducing natural and regular bowel movement by reaching and correcting the cause of constipation by strengthening and toning the muscles controlling defecation; that it would improve and strengthen the body, not weaken or injure it; that it would be efficacious in the treatment of piles and troubles caused by faulty elimination; that it would restore the sphincter muscles to a normal condition, relieve congestion of blood and establish a healthy, vigorous circulation; would relieve constipation of long standing; would bring health and comfort and promote more refreshing sleep, and would be efficacious to aid nature in conditions commonly associated with constipation such as coated tongue, foul breath, bad taste in the mouth, sallow skin, acne, erythema, urticaria, anemia, lassitude, mental hebetude, insomnia, more or less marked degree of anorexia, headache, "spurious" diarrhea, colicky pains caused by enterospasm, neuralgic pains, hemorrhoids, fissure pruritus, occasional prolapse, auto-intoxication, flatulence, indigestion, nervousness, irritability, and cold extremities; that recovery would be permanent and that one need have no fear of using it too long or too much, were false and misleading, since the article would not be efficacious for such purposes and might be used too long or too much.

The dilator was alleged to be misbranded further in that it would be dangercus to health when used with the frequency and duration prescribed, recommended, or suggested in the following labeling: (Carton) "Adults begin with No. 1 Dilator. First warm dilator in warm water; then lubricate outside of dilator with Dr. Young's Piloment (or if it is not available, with vaseline) and while in a squatting position—or while lying on the side with knees drawn up—gently insert in the rectum as far as the flange or rim. Hold in place a minute and the anal muscles will close and retain it. Sit or lie down and allow it to remain for half an hour or an hour to get the best results. Ten minutes will accomplish much. When ready to go to the next larger size, it is best first to use for a few minutes the same size you have been using, inserting and withdrawing it several times. This is very beneficial and should not be overlooked. Children. The Dilators should not be used by any child under 8 years except under the instructions of a physician. An 8 to 12 year old child may use progressively our Nos. 0, 1 and 1½ Dilators. * * * Directions for use are the same as in the above paragraph for adults. Any larger sizes than these for children of these ages should be used only under direction of a physician. Children from 12 to 18 years should follow the same directions as those given for children from 8 to 12 years except that they may use the Nos. 2 and 2½ Dilators after they have used the smaller sizes according to directions. Try to use the Dilators each day; * * * Keep your Dilators and make occasional use of them. * * * Important: Do not neglect to use your Dilators; * * * It is advisable to use occasionally as a precautionary measure. You need have no fear of using them too much."

Dr. Young's Piloment was alleged to be misbranded in that representations in the labeling that it would promote healing of piles, and that in conjunction with Dr. Young's Dilators it would be efficacious in the treatment of rectal irritation, and would be efficacious as an auxiliary treatment and relief of constipation and piles, was a soothing treatment for itching and bleeding piles, and would help in a more speedy recovery from piles, were false and misleading since it would not be efficacious for such purposes.

On December 6, 1940, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

Nos. 336 to 339 report the seizure and disposition of intra-cervical or intra-uterine types of metal or rubber-covered stem pessaries which were potentially dangerous.

336. Misbranding of pessaries. U. S. v. 2 Small and 6 Medium-Sized Pessaries (and 1 other seizure action against pessaries). Default decrees of condemnation and destruction. (F. D. C. Nos. 2542, 2646. Sample Nos. 8936–E, 27361–E, 27362–E, 27363–E.)

On August 15 and October 1, 1940, the United States attorneys for the Northern District of Ohio and the District of Minnesota filed libels (the former amended on or about September 25, 1940) against 2 small and 6 medium-sized pessaries at Toledo, Ohio; and 5 small, 7 medium-sized, and 9 large pessaries at Minne-

apolis, Minn., alleging that the article had been shipped in interstate commerce within the period from on or about February 15 to on or about July 29, 1940, by H. Carstens Manufacturing Co. from Chicago, Ill.; and charging that it was misbranded in that it was dangerous to health when used with the frequency or duration prescribed. The article was labeled in part "X. L. Gold Pessary."

On November 15, 1940, and February 10, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

337. Misbranding of pessaries. U. S. v. 18 Small and 47 Medium-Sized Pessaries. Default decree of condemnation and destruction. (F. D. C. No. 2671. Sample Nos. 15870–E to 15873–E, incl.)

On August 23, 1940, the United States attorney for the Eastern District of Missouri filed a libel against 18 small and 47 medium-sized pessaries at St. Louis, Mo., alleging that the article had been shipped in interstate commerce within the period from on or about April 11 to on or about August 1, 1940, by the Gomco Surgical Manufacturing Corporation from Buffalo, N. Y.; and charging that it was misbranded in that it was dangerous to health when used with the frequency or duration prescribed. The article was labeled in part: "Gomco Perfect Pessary * * * Small [or "Medium"] Size."

On September 21, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

338. Misbranding of pessaries. U. S. v. 1 Large, 10 Regular, and 4 Small-Sized Cone Pessaries (and 1 other seizure action against pessaries). Default decrees of condemnation and destruction. (F. D. C. Nos. 2714, 2780. Sample Nos. 5331–E, 6708–E.)

On August 31 and September 10, 1940, the United States attorneys for the District of Utah and the Northern District of Ohio filed libels against 1 large, 10 regular, and 4 small pessaries at Salt Lake City, Utah; and 6 large, 23 regular, and 6 small pessaries at Cleveland, Ohio, alleging that the article had been shipped in interstate commerce on or about March 6 and August 19, 1940, by the Medex Supply Co. from Denver, Colo.; and charging that it was misbranded. The article was labeled in part: "Flexible Large Size [or "Regular" or "Small Size"] Kone Pessary."

The article was alleged to be misbranded in that it was dangerous to health when used with the frequency or duration prescribed, recommended, or suggested in the following statements in the labeling: "1—Immerse the Flexible Kone Pessary in alcohol or some other good germicidal solution and dry it. 2—Place small capsule over prongs after bringing them together. 3—Fold the soft rubber button (see fig. 4) and grasp with lock forceps. 4—With patient in a dorsal recumbent position, the speculum in place, start the pessary into the os uteri with a slight rotating or up and down motion. The pessary will find the entire length of the canal without the knowledge of the patient. 5—Hold the pessary in place for one or two minutes to allow the gelatine capsule to dissolve, thus liberating the prongs. 6—Carefully remove the speculum so as to avoid displacing the pessary. 7—In conditions where there is a marked flexion of the cervical canal, the insertion of the small end of a Sterling dilator or other suitable instrument is advised, in order to be certain that the canal is open." The lot seized at Cleveland, Ohio, was alleged to be misbranded further in that the statement "Scientific Safe" borne on the label, was false and misleading.

On October 12 and December 4, 1940, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

339. Misbranding of pessaries. U. S. v. 12 Pessaries. Default decree of condemnation and destruction. (F. D. C. No. 2625. Sample Nos. 27373–E, 27374–E.)

On August 21, 1940, the United States attorney for the Northern District of Ohio filed a libel against 12 pessaries at Cleveland, Ohio, alleging that the article had been shipped in interstate commerce within the period from on or about June 10 to on or about July 3, 1940, by the Penn Surgical Manufacturing Co., Inc., from Philadelphia, Pa.; and charging that it was misbranded in that it was dangerous to health when used with the frequency or duration prescribed. The article was labeled in part: "Penn Plated #1 [or "#3," "#4," "#5," or "#6."]"

On September 23, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

340. Misbranding of Fru-Lax. U. S. v. 3 Cans and 20 Cans of Fru-Lax. Default decree of condemnation and destruction. (F. D. C. No. 2436. Sample No. 30048–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the treatment of the conditions indicated hereinafter and failed to bear the names of the active ingredients and adequate directions for use, and such adequate warnings as are necessary for the protection of users.

On July 29, 1940, the United States attorney for the Eastern District of Wisconsin filed a libel (amended August 16, 1940) against 3 3-ounce cans and 20 12-ounce cans of Fru-Lax at Racine, Wis., alleging that the article had been shipped in interstate commerce on or about April 8 and July 9, 1940, by the Fru-Lax Co. from Chicago, Ill.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of purging cassia tissues, senna-leaf tissues, and carob-bean tissues.

The article was alleged to be misbranded in that representations in the labeling that it was not habit-forming; that it would restore and enable one to regain health; would relieve ailments caused by poisons absorbed from the bowels; that it was efficacious in the treatment of rheumatism, neuritis, stomach trouble, gall-bladder trouble, headaches, catarrh, skin trouble, excessive gas, colds, piles, high blood pressure; that it was of value in reducing; was an ideal neutralizer, would help make the body disease-proof; and that it possessed the rejuvenating and restorative properties implied in the statements "Return to Nature * * * Don't feel 'old at 40'," were false and misleading since the use of the article might result in the laxative habit, and it would not be efficacious for the purposes for which it was so recommended. It was alleged to be misbranded further in that the label did not bear the common or usual names of the active ingredients; in that the label did not bear adequate directions for use; and in that the label did not bear such adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users.

On October 23, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

341. Misbranding of Maurice Le Bell's Formula No. 7. U. S. v. 143 Bottles of Maurice Le Bell's Formula No. 7. Default decree of condemnation and destruction. (F. D. C. No. 3297. Sample Nos. 30415–E, 30417–E.)

The label of this product contained false and misleading representations regarding its efficacy for the conditions indicated below. Furthermore, its labeling failed to bear adequate directions for use.

On November 4, 1940, the United States attorney for the Northern District of Illinois filed a libel against 143 bottles of the above-named product at Chicago, Ill., alleging that the article had been shipped in interstate commerce on or about September 11, 1940, by Hollywood Formulas, Inc., from Los Angeles, Calif.; and charging that it was misbranded.

Analysis showed that the article consisted of tablets containing Irish moss, rhubarb root, seaweed such as *Laminaria*, parsley leaf, cranberry fruit, and leaves resembling celery.

The article was alleged to be misbranded in that the following statements in the labeling were false and misleading, since the article was not efficacious for the purposes recommended therein: (Bottle) "As Recommended by Hollywood's Famous Dr. Maurice Le Bell, D. C. Reducing Specialist"; (booklet) "The Reducing Method of Dr. Maurice LeBell, D. C. to be Used in Connection with Formula No. 7 * * * Important * * * The instructions contained in this booklet are a vital part of your reducing program, and should be studied carefully. They are a simplified form of the famous reducing method used by Dr. Maurice LeBell, D. C., in his many years of private practice. * * * Best results are obtained by following these instructions carefully * * * We suggest that you take a full length front and profile snapshot of yourself today. Many people have reported a second picture taken at the end of their supply of Formula showed most gratifying results." It was alleged to be misbranded further in that the directions for use appearing on the bottle and in the booklet. "Take 8 tablets daily, 3 before breakfast and dinner and 2 before retiring. (See exercise and diet booklet.)

Decrease dosage in accordance with degrees of laxation required," were inappropriate for the article, since they suggested frequent and continuous consumption and were therefore inadequate.

On January 28, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

342. Misbranding of Slendotabs. U. S. v. 80 Packages of Slendotabs. Default decree of condemnation and destruction. (F. D. C. No. 2532. Sample No. 16769–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter. The article contained strychnine, which fact was not declared on the label. Its labeling also failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users.

On or about August 16, 1940, the United States attorney for the Western District of Missouri filed a libel against 80 packages of Slendotabs at Kansas City, Mo., alleging that the article had been shipped in interstate commerce on or about May 18, 1940, by Keneco Products from Elmira, N. Y.; and charging that it was misbranded.

Analysis showed that each tablet of the article contained approximately ½ grain of phenolphthalein, a resinous drug such as leptandra resin, compounds of iodine equivalent to 0.088 grain of iodine per tablet, and alkaloidal material including strychnine.

The article was alleged to be misbranded (1) in that its labeling represented that it would be efficacious in reducing excessive fat, that it was a scientifically balanced weight reduction method, and would help eliminate waste matter and accumulated poisons from the body, which representations were false and misleading since the article would not constitute an adequate or appropriate treatment for such purposes; (2) in that the labeling was misleading in that it failed to reveal that the article contained strychnine, a material fact in the light of the statement on the carton that the active ingredients were phenolphthalein, calcium iodized, and leptandrin. It was alleged to be misbranded further in that its label failed to bear a statement of the presence of and quantity of strychnine contained therein; in that its labeling failed to bear adequate directions for use, since the directions on the carton, "Take one or two tablets immediately before each meal, three times a day. For best results, take tablets regularly and faithfully, as directed. As these tablets are laxative, not more than six tablets should be taken in 24 hours," and the directions in the leaflet were not appropriate for an article of such composition and was therefore inadequate. It was alleged to be misbranded further in that the labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health and against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users, since the labeling did not inform the purchaser of the danger involved in the use of the article in cases of appendicitis, nor did it warn that frequent or continued use might result in dependence upon laxatives, nor did the label reveal the fact the the use of the article might result in skin eruptions.

On October 23, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

343. Misbranding of Venus Tablets. U. S. v. 66 Cartons and 80 Cartons of Venus Tablets. Default decrees of condemnation and destruction. (F. D. C. Nos. 2265, 4094. Sample Nos. 30305–E, 31965–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter and failed to bear adequate directions for its use and such adequate warnings as are necessary for the protection of users. It was also deceptively packaged.

On June 25, 1940, and April 10, 1941, the United States attorney for the Northern District of Illinois filed libels against 146 cartons of Venus Tablets at Chicago, Ill., alleging that the article had been shipped in interstate commerce on or about May 6 and September 22, 1940, by the Thoro Sales Service from Los Angeles, Calif.; and charging that it was misbranded.

Each carton contained a bottle labeled "Venus Tablets" and an envelope labeled "Sample Tablets V–76 Laxative Tablets." Analyses showed that the Venus Tablets contained rhubarb root, kelp, Irish moss, and green leafy material; and that the V–76 Tablets contained dried rhubarb root, cranberries, and green leafy mate-

rial. The carton was nearly 1 inch taller than was necessary to hold the bottle and sample.

The article was alleged to be misbranded in that its labeling was false and misleading since it created the impression that the article, by virtue of its physiological activity, would have a substantial effect in the control of body weight, would enable one to arrive at a satisfactory weight, would enable one to attain an ideal and slender form, and would cause one to lose ugly fat, feel better and look better; whereas it would not be efficacious for such purposes.

It was alleged to be misbranded further in that its labeling failed to bear adequate directions for use of the Venus Tablets and V–76 Laxative Tablets and failed to bear adequate warnings against their use by children or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users. It was alleged to be misbranded further in that its container, i. e., carton, was so made, formed, or filled as to be misleading.

On October 21, 1940, and May 13, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

344. Misbranding of Wittone. U. S. v. 180 Dozen Bottles of Wittone. Default decree of condemnation and destruction. (F. D. C. No. 2331. Sample No. 1662–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter. Its labeling was further objectionable because of misleading representations regarding the quantities of certain minerals present, regarding its alleged tonic effects and because of failure to bear adequate directions and adequate warnings as required by law.

On July 8, 1940, the United States attorney for the District of Columbia filed a libel against 180 dozen bottles of Wittone at Washington, D. C., alleging that the article was being offered for sale in the District of Columbia at the Wittone Sales Agency of United Distributors, Inc., of Louisville, Ky., at Washington, D. C.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of a water solution of Epsom salt (29.5 grams per 100 cc.) together with essentially inconsequential proportions of iron and ammonium citrate (0.8 gram per 100 cc.), sodium salicylate (0.5 gram per 100 cc.), sodium phosphate (0.7 gram per 100 cc.), sodium bicarbonate, and flavoring materials.

The article was alleged to be misbranded in that representations in the labeling that it was efficacious for the health, would help one eat well, sleep well, and keep well; that it was efficacious in bilious spells, dizziness, headaches, sour stomach, dull tired-out feeling, coated tongue, bad taste, and loss of appetite; that it was efficacious to correct the results of over-indulgence and constipation; would correct the cause of restless nights; that it was a mild diuretic and would stimulate elimination of urea and uric acid, regulate elimination, keep the system free from impurities, aid the blood, and cleanse the intestinal tract, were false and misleading since it would not be efficacious for such purposes.

It was alleged to be misbranded further in that the word "Tone," forming a part of the name "Wittone" appearing in the labeling, was false and misleading because the article contained no significant amount of tonic ingredient and would not act as a tonic. It was alleged to be misbranded further in that the statements in the labeling, "Ingredients—Epsom Salts (Magnesium Sulphate), 3.3 oz. Iron and Ammonium Citrate, 40 grs.; Sodium Salicylate, 27 grs.; Sodium Phosphate, 27 grs.; Sodium Bicarbonate, 40 grs.; Oil of Cassia, 2$\frac{7}{10}$ min.; Oil of Cloves, $\frac{9}{10}$ min.; Saccharine, 3$\frac{6}{10}$ min.," were false and misleading since they failed to reveal the material fact that the amounts of iron and ammonium citrate, sodium salicylate, sodium phosphate, and sodium bicarbonate in the product, were in inconsequential proportions when the medicine was consumed in accordance with the directions in the labeling.

It was alleged to be misbranded further in that the statements in the labeling, (contact card) "Please Contact: Name ——— Address ——— City ——— State ——— I am confident he will be relieved of ——— through the consistent use of Wittone as I have been benefited," and the statements (business reply card) "Wittone Representative: I would like to use Wittone. Please deliver to me a bottle of your Famous and Celebrated Medicine for I believe Wittone will benefit me as it has countless other suffering people," were false and misleading since it was not efficacious for the purposes recommended.

It was alleged to be misbranded further in that the labeling failed to bear adequate directions for use since the directions appearing on the bottle, as follows, "Adults—1 to 2 tablespoonfuls once or twice a day in water before

eating. Children—1 teaspoonful to a tablespoonful as above. General Directions. Wittone is full-strength, with a pure, sharp taste. Adults should take About two tablespoonfuls twice a day in a glass of water before eating. Please note we say 'about' two tablespoonfuls. We say this because we do not believe it is possible to prepare directions which will fit all people. Perhaps you should take a trifle more than two tablespoonfuls as your dose. Or, you may find that less than two tablespoonfuls is your proper dose. You can easily determine this soon after you start using the medicine and should then continue to take your proper dose twice daily. Laxatives should not be used continuously so that the bowels may resume their normal action. For Children up to 10 years of age, two teaspoonfuls more or less, two times a day as for adults, later reducing to one dose per day for a sufficient period," were not appropriate for the product and were not adequate.

It was alleged to be misbranded further in that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health and against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users since there was no warning against the administration of the medicine to young children to whom its use might be dangerous nor against frequent or continued use of the article which might result in the establishment of dependence upon laxatives.

On August 16, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

CRIMINAL PROSECUTIONS

345. Adulteration and misbranding of Heron's Pure Eucalyptus Oil. U. S. v. Norman C. Heron (N. C. Heron Co.). Tried to the court and jury. Verdict of guilty. Fine, $300. (F. D. C. No. 2091. Sample No. 97364–D.)

This product did not meet the requirements of the United States Pharmacopoeia for eucalyptus oil. Its labeling also bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On September 12, 1940, the United States attorney for the Southern District of California filed an information against Norman C. Heron, trading as N. C. Heron Co., Los Angeles, Calif., alleging shipment on or about November 23, 1939, from the State of California into the State of Idaho, of a quantity of Heron's Pure Eucalyptus Oil which was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia but its strength differed from, and its quality and purity fell below, the standard set forth in that compendium in that it contained not more than 68 percent of eucalyptol and was not soluble in 5 volumes of 70 percent alcohol; whereas the United States Pharmacopoeia provides that eucalyptus oil shall contain not less than 70 percent of eucalyptus and shall be soluble in 5 volumes of 70 percent alcohol, and the difference in strength, quality, and purity of the article from the standard for eucalyptus oil set forth in the said compendium was not stated plainly on its label.

The article was alleged to be misbranded in that the statements borne on the bottle label were false and misleading since they represented that it was pure eucalyptus oil; that it was an all-around family remedy, and was efficacious for internal or external use from the youngest to the oldest; that said article, when used alone or in connection with Heron's Liver Regulator, had no equal in the treatment of Bright's disease and diabetes; that it was the only remedy without an enemy, implying that it was a remedy approved by everyone; that it was efficacious in the treatment of anything that originated from a cold; that it was efficacious in the treatment of cough, whooping cough, croup, sore throat, diphtheria, pleurisy, pneumonia, fever, stomach and kidney troubles, diabetes, catarrh, asthma, bronchitis, headache, earache, toothache, neuralgia, burns, poison oak, wounds of all kinds, consumption in its first stages, fever of all kinds, rheumatism, gravel, dyspepsia, kidney disease, and cuts; whereas it was not pure eucalyptus oil and was not efficacious for the said purposes.

On October 25, 1940, the defendant having entered a plea of not guilty, the case came on for trial before the court and jury. The trial was concluded

on October 28, 1940, on which date the court delivered the following instructions to the jury:

HARRISON, *District Judge.* "You have listened to counsel on both sides, and now you will have to listen to the court for a few moments as I read the instructions to you.

"By the filing of an information, no presumption whatsoever arises to indicate that a defendant is guilty, or that he has had any connection with, or responsibility for, the act charged against him. A defendant is presumed to be innocent at all stages of the proceeding until the evidence introduced on behalf of the Government shows him to be guilty beyond a reasonable doubt. And this rule applies to every material element of the offense charged. Mere suspicion will not authorize a conviction. A reasonable doubt is such a doubt as you may have in your minds when, after fairly and impartially considering all of the evidence, you do not feel satisfied to a moral certainty of the defendant's guilt. In order that the evidence submitted shall afford proof beyond a reasonable doubt, it must be such as you would be willing to act upon in the most important and vital matters relating to your own affairs.

"Reasonable doubt is not a mere possible or imaginary doubt or a bare conjecture; for it is difficult to prove a thing to an absolute certainty.

"You are to consider the strong probabilities of the case. A conviction is justified only when such probabilities exclude all reasonable doubt as the same has been defined to you. Without it being restated or repeated, you are to understand that the requirement that a defendant's guilt be shown beyond a reasonable doubt is to be considered in connection with and as accompanying all the instructions that are given to you.

"In judging of the evidence, you are to give it a reasonable and fair construction, and you are not authorized, because of any feeling of sympathy or other bias, to apply a strained construction, one that is unreasonable, in order to justify a certain verdict when, were it not for such feeling or bias, you would reach a contrary conclusion. And whenever, after a careful consideration of all of the evidence, your minds are in that state where a conclusion of innocence is indicated equally with a conclusion of guilt, or there is a reasonable doubt as to whether the evidence is so balanced, the conclusion of innocence must be adopted.

"You are the sole judges of the credibility and the weight which is to be given to the different witnesses who have testified upon this trial. A witness is presumed to speak the truth. This presumption, however, may be repelled by the manner in which he testifies; by the character of his testimony, or by evidence affecting his character for truth, honesty, and integrity or his motives; or by contradictory evidence. In judging the credibility of the witnesses in this case, you may believe the whole or any part of the evidence of any witness, or may disbelieve the whole or any part of it, as may be dictated by your judgment as reasonable men. You should carefully scrutinize the testimony given, and in so doing consider all of the circumstances under which any witness has testified, his demeanor, his manner while on the stand, his intelligence, the relations which he bears to the Government or the defendant, the manner in which he might be affected by the verdict and the extent to which he is contradicted or corroborated by other evidence, if at all, and every matter that tends reasonably to shed light upon his credibility. If a witness is shown knowingly to have testified falsely on the trial touching any material matter, the jury should distrust his testimony in other particulars, and in that case you are at liberty to reject the whole of the witness' testimony.

"There is nothing peculiarly different in the way a jury is to consider the proof in a criminal case from that by which men give their attention to any question depending upon evidence presented to them. You are expected to use your good sense, consider the evidence for the purposes only for which it has been admitted, and in the light of your knowledge of the natural tendencies and propensities of human beings, resolve the facts according to deliberate and cautious judgment; and while remembering that the defendant is entitled to any reasonable doubt that may remain in your minds, remember as well that if no such doubt remains the Government is entitled to a verdict. Jurors are expected to agree upon a verdict where they can conscientiously do so; you are expected to consult with one another in the jury room and any juror should not hesitate to abandon his own view when convinced that it is erroneous. In determining what your verdict shall be you are to consider only the evidence before you. Any testimony as to which an objection was

sustained, and any testimony which was ordered stricken out, must be wholly left out of account and disregarded. The opinon of the judge as to the guilt or innocence of a defendant, if directly or inferentially expressed in these instructions, or at any time during the trial, is not binding upon the jury. For to the jury exclusively belongs the duty of determining the facts. The law you must accept from the court as correctly declared in these instructions.

"Should you believe that Heron's Pure Eucalyptus Oil contains some ingredient which you believe to have a therapeutic or curative value in the treatment of the disease for which it is recommended, then there is no misbranding as to such disease.

"You are charged that to establish the fact that Heron's Pure Eucalyptus Oil is misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act and as charged in the information, the Government must prove beyond a reasonable doubt:

"That the labeling carries some statement regarding the contents of Heron's Pure Eucalyptus Oil which is false and misleading in some particular; and

"That the statements made on the labeling regarding the curative or therapeutic effects of Heron's Pure Eucalyptus Oil are false and misleading; and

"Such false and misleading labeling must be established by competent proof and by credible and convincing evidence.

"You are instructed that, among other things, before you can find the defendant guilty of count I, you must find that Heron's Pure Eucalyptus Oil is a drug that is recognized in the United States Pharmacopoeia and that the strength of Heron's Pure Eucalyptus Oil differed from, and its quality and purity fell below, the standard set forth in the United States Pharmacopoeia in that Heron's Pure Eucalyptus Oil contained only 68 percent eucalyptol and that Heron's Pure Eucalyptus Oil is not soluble in 5 volumes of 70 percent alcohol; and should you so find as I have above instructed you, before you can find the defendant guilty you must find further that the fact that Heron's Pure Eucalyptus Oil contains but 68 percent eucalyptol and is not soluble in 5 volumes of 70 percent alcohol as the test prescribed by the United States Pharmacopoeia to test the strength, quality, and purity of Heron's Pure Eucalyptus Oil and unless you so find, you must find the defendant not guilty of count I.

"If the evidence in this case, as to any particular count, is susceptible of two constructions or interpretations, each of which appears to you to be reasonable, and one of which points to the guilt of the defendant, and the other to his innocence, it is your duty under the law to adopt that interpretation which will admit of the defendant's innocence, and reject that which points to his guilt.

"You are further instructed that if any material claim or statement on either the label, carton, or circular is false or misleading then, regardless of the intent of the mind of the defendant, you are to find the defendant guilty.

"You are instructed that it is against the law of the United States for any person to introduce or deliver for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

"You are further instructed that a drug or device shall be deemed to be adulterated if it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium.

"You are further instructed that the Pharmacopoeia of the United States, Volume XI, is an official compendium.

"You are further instructed that a drug or device shall be deemed to be misbranded if its label is false or misleading in any particular.

"You are further instructed that the term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers or (2) accompanying such article.

"You are further instructed that if you find, from the evidence in this case, that Norman C. Heron did on or about November 21, 1939, deliver a package of Heron's Pure Eucalyptus Oil to an agent of the Railway Express Co. in Los Angeles, Calif., addressed to Nelson Drug Co. at Gooding, Idaho, and that said Railway Express Co. did send said package to Gooding, Idaho, you are to find that said package was introduced or delivered for introduction into interstate commerce.

"You are further instructed that if you find, from the evidence introduced in this case, beyond a reasonable doubt, that Norman C. Heron did on or about November 23, 1939, introduce into interstate commerce, a package of Heron's Pure Eucalyptus Oil at Los Angeles, Calif., consigned to Nelson's Drug Store, Gooding, Idaho, that said eucalyptus oil fell below the standards required for oil

of eucalyptus as set forth in the Pharmacopoeia of the United States, Volume XI, then you are to find the defendant Norman C. Heron guilty as charged in count I of the information.

"You are instructed that if you find, from the evidence introduced in this case, beyond a reasonable doubt, that Norman C. Heron did on or about November 23, 1939, introduce into interstate commerce a package of Heron's Pure Eucalyptus Oil at Los Angeles, Calif., said package being consigned to Nelson's Drug Store, Gooding, Idaho; that in said packages were labels, cartons, and circulars containing false and misleading statements as to the curative and therapeutic efficacy of said Heron's Pure Eucalyptus Oil, then you are to find the defendant Norman C. Heron guilty as charged in count II of the information.

"I have advised you that the defendant is charged with having violated certain provisions of what is known as the 'Food and Drugs Act,' the purpose of which was and is to protect consumers against impure and adulterated food and drugs, and also against the use of food or drugs which do not show what they contain by the brands on the packages; or which are misbranded or which contain misleading claims pertaining to the therapeutic and curative efficacy of the product. The prohibition of this act is directed only against the introduction into interstate commerce of any article of food, drink, or of any drug either adulterated or misbranded. In arriving at your decision in this case you are not concerned with the wisdom of this act of Congress in passing the Food and Drugs Act. You are only concerned with the facts in this case. You must determine what the facts are in relation to the issue which is formed by the information filed and the plea entered by the defendant.

"Ordinarily, in the trial of cases in court, witnesses are confined in their testimony to facts within their personal knowledge and they are not permitted to draw conclusions or express opinions. That is the general rule, but there is an exception to that rule where the points in issue arise out of a particular science or art concerning which there are trained minds who have special knowledge, learning, or schooling in that particular field. Such persons are called experts and because of that special training or learning they are entitled to express opinions concerning the matters at issue. You will, of course, weigh and evaluate the testimony of the expert witnesses in this case precisely as you weigh the testimony of any nonexpert witnesses; that is to say, you will take into account the probability and reasonableness of the matters to which they have testified, the schooling of the person giving it, the learning that he has in his profession, or the want of it, and the breadth of his experience in the field which would enable him to arrive at a correct conclusion. In other words, his testimony should be given such weight as you believe it is entitled to receive.

"Under the Federal Food and Drugs Act the term 'drug' includes any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of mankind. The aim of the act is to prevent indirection and ambiguity in the labeling of drugs, as well as to prevent statements which are literally false. It is not difficult to choose statements, designs, or devices concerning the curative or therapeutic effect of an article of drugs which will not deceive. Those which are ambiguous and likely to mislead should be read favorably to the accomplishment of the purposes of the act and, if you find the labels used by the defendant, Norman C. Heron, describing the curative and therapeutic effect of the article or drug, Heron's Pure Eucalyptus Oil, contain statements that are likely to mislead, you should find the defendant guilty of misbranding.

"If you find that the circulars introduced in evidence in this case were contained in the packages admitted to have been shipped in interstate commerce by the defendant, and if you further find that said circulars contain statements describing the curative and therapeutic effect of the article or drug, Heron's Pure Eucalyptus Oil, and if you further find that such statements are likely to mislead, you should find the defendant guilty of misbranding.

"The Food and Drugs Act is plain and direct. Its comprehensive terms condemn every statement, design, and device which may mislead or deceive and which are falsey and fraudulently made. Deception may result from use of statements not technically false or which may be literally true. The law is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult for one making and distributing drugs in interstate commerce to choose statements, designs, and devices which will not deceive. That is his duty when engaged in such business. Too, statements which are ambiguous and likely to mislead should be read favorably to the accomplishment of the aims and purposes of the Food and Drugs Act.

"This is important legislation intended to protect the people so far as this case is concerned from the transportation and sale of misbranded medicines, experience having shown that men and women afflicted with disease are disposed to try a professed remedy, no difference how useless or even harmful it may be if it is strongly recommended, and it is to protect the sick and afflicted and people who are easily imposed upon, from fraudulent practices of the unprincipled and avaricious that this law was passed. It is a wise law and in proper cases should be rigidly enforced.

"If, after hearing the evidence in this case, you reach the conclusion that the drug or product known as 'Heron's Pure Eucalyptus Oil' was harmless, that does not excuse the defendant, if you find that he placed statements upon said drugs which were false, concerning the curative and therapeutic effects of said products, as the danger and injury to the public from representations of this type is considerable in that it induces persons frequently to rely in serious cases upon preparations without healing virtue when, but for this reliance, they would no doubt secure proper advice and treatment for the ills which affect them.

"If, in these instructions, any rule, direction, or idea be stated in varying ways, no emphasis thereon is intended by me, and none must be inferred by you. For that reason, you are not to single out any certain sentence, or any individual point or instruction, and ignore the others, but you are to consider all the instructions and as a whole, and to regard each in the light of all the others.

"At times throughout the trial the court has been called upon to pass on the question whether or not certain offered evidence might properly be admitted. With such rulings and the reasons for them you are not to be concerned. Whether offered evidence is admissible is purely a question of law, and from a ruling on such a question you are not to draw any inference as to what weight should be given the evidence, or as to the credibility of a witness. In admitting evidence to which an objection is made, the court does not determine what weight should be given such evidence. As to any offer of evidence that was rejected by the court, you, of course, must not consider the same; as to any question to which an objection was sustained, you must not conjecture as to what the answer might have been or as to the reason for the objection.

"You are instructed that if the judge has said or done anything which has suggested to you that he is inclined to favor the claims or position of either party, you will not suffer yourself to be influenced by any such suggestion.

"I have not expressed, nor intended to express, nor have I intimated nor intended to intimate, any opinion as to what witnesses are, or are not, worthy of credence; what facts are, or are not, established; or what inferences should be drawn from the evidence adduced. If any expression of mine has seemed to indicate an opinion relating to any of these matters, I instruct you to disregard it.

"The verdict to be rendered must represent the considered judgment of each juror.

"In order to return a verdict it is necessary that each juror agree thereto. Your verdict must be unanimous.

"When you retire to your jury room to deliberate, you will select one of your number as foreman and he will sign your verdict for you when it has been agreed upon. You will then return into court with the verdict and your foreman will represent you as your spokesman in the further conduct of this case in this court.

"Forms of verdicts have been prepared for your convenience, and when you have agreed upon a verdict, the foreman will sign the verdict upon which you agree and return it into court.

"Are there any exceptions on any of these instructions?"

Mr. COTTER. "No, your honor."

THE COURT. "The clerk will now swear the officers to take charge of the jury."

(Whereupon the officers were duly sworn to take charge of the jury.)

THE COURT. "The court will hand you the form of verdict, and you will now retire to the jury room for your deliberations.

"Is it stipulated that the jury may have the exhibits?"

Mr. COTTER. "So stipulated."

Mr. LAW. "So stipulated."

The jury thereupon retired and after due deliberation returned a verdict of guilty. The court suspended the sentence on the first count for a period of 2 years, and sentenced the defendant to 6-months' imprisonment on the second count, which was also suspended for 2 years and the defendant was placed on probation for that period. The court also imposed a fine of $300.

346. Adulteration of solution citrate of magnesia. U. S. v. Joseph D. Mehlman and Robert P. Friedman (F. & M. Chemical Co.). Pleas of guilty. Fine of $100 as to Joseph D. Mehlman and $1 as to Robert P. Friedman. (F. D. C. No. 2086. Sample No. 64997–D.)

This product differed in strength from the pharmacopoeial standard.

On July 23, 1940, the United States attorney for the Southern District of Indiana filed a libel against Joseph D. Mehlman and Robert P. Friedman, copartners trading as F. & M. Chemical Co., at Indianapolis, Ind., alleging shipment on or about January 10, 1940, from the State of Indiana into the State of Kentucky of a quantity of a product labeled in part, "Effervescing Solution Citrate of Magnesia," that was adulterated

The article was alleged to be adulterated in that it purported to be and was represented as a drug which is recognized in an official compendium, i. e., the United States Pharmacopoeia, under the name "Solution of Magnesium Citrate," but its strength differed from the standard set forth in such compendium in that each 100 cubic centimeters of the article contained an amount of magnesium citrate corresponding to less than 1.6 grams of magnesium oxide, namely, an amount of magnesium citrate corresponding to not more than 1.49 grams of magnesium oxide; and 10 cubic centimeters of said article contained total citric acid equivalent to less than 26 cubic centimeters, namely, not more than 23.16 cubic centimeters of half-normal hydrochloric acid; whereas the United States Pharmacopoeia provides that solution of magnesium citrate shall contain, in each 100 cubic centimeters an amount of magnesium citrate corresponding to not less than 1.6 grams of magnesium oxide, and that 10 cubic centimeters of the solution shall contain total citric acid equivalent to not less than 26 cubic centimeters of half-normal hydrochloric acid; and the difference in the strength of the article from the standard set forth in the United States Pharmacopoeia was not plainly stated on its label.

On September 26, 1940, the defendants having entered pleas of guilty, the court imposed a fine of $100 against Joseph D. Mehlman and $1 against Robert P. Friedman.

347. Adulteration and misbranding of sandalwood oil. U. S. v. Alfred C. Hoffman (trading as Red Mill Drug Co.). Plea of guilty. Defendant sentenced to 10 months' imprisonment, sentence suspended and defendant placed on probation for 1 year. (F. D. C. No. 2079. Sample Nos. 77631–D, 77632–D, 86606–D to 86608–D, incl.)

This product differed from the pharmacopoeial standard in the following respects: It yielded less than 90 percent of alcohols calculated as santalol, it did not have the characteristic odor of sandalwood, and was not soluble in 5 volumes of 70 percent alcohol. It also differed from the standard with respect to its specific gravity, optical rotation, and refractive index.

On November 7, 1940, the United States attorney for the Eastern District of New York filed an information against Alfred C. Hoffman, trading as the Red Mill Drug Co. at Brooklyn, N. Y., alleging shipment within the period from on or about August 25 to on or about October 24, 1939, from the State of New York into the States of Pennsylvania and Massachusetts of quantities of sandalwood oil that was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be or was represented as a drug the name of which is recognized in the United States Pharmacopoeia; but its strength differed from, and its quality and purity fell below the standard set forth in that compendium, and its difference in strength, quality, and purity from such standard was not plainly stated on its label.

It was alleged to be misbranded in that the statement "Pure East India (U. S. P.) Sandalwood Oil" with respect to all lots, and the statement "Each Capsule Contains 5 Minims" with respect to one lot, borne on the labels, were false and misleading in that they represented that the article was sandalwood oil which conformed to the standard laid down in the United States Pharmacopoeia, and that in the case of one of the lots each capsule contained 5 minims thereof, whereas it was not sandalwood oil which conformed to the standard laid down in such compendium, and the capsules in one lot contained less than 5 minims thereof. It was alleged to be misbranded further in that it was an imitation of sandalwood oil and was offered for sale under the name of another article, i. e., "Pure East India (U. S. P.) Sandalwood Oil."

The information also charged the defendant with various other shipments of sandalwood oil that was adulterated and misbranded in violation of the Federal Food and Drugs Act of 1906, as reported in notices of judgment published under that act.

On January 7, 1941, a plea of guilty having been entered, the court sentenced the defendant to 10 months' imprisonment on the 10 counts covering violations of the Federal Food, Drug, and Cosmetic Act, but suspended sentence and placed the defendant on probation for 1 year. (On each of the 8 counts charging violation of the Federal Food and Drugs Act of 1906 the court imposed a fine of $1.)

348. Adulteration and misbranding of elixir iron, quinine, and strychnine phosphates; and of ammoniated mercury ointment. U. S. v. Standard Pharmaceutical Corporation. Plea of guilty. Fine, $50 and costs. (F. D. C. No. 2889. Sample Nos. 1457–E, 1463–E.)

These products were represented to be drugs the names of which are recognized in official compendiums and their strength differed from and their quality fell below the standard set forth therein.

On January 31, 1941, the United States attorney for the District of Maryland filed an information against the Standard Pharmaceutical Corporation, Baltimore, Md., alleging shipment on or about April 18, 1940, from the State of Maryland into the District of Columbia of quantities of elixir of iron, quinine, and strychnine phosphates and of ammoniated mercury ointment which were adulterated and misbranded.

The elixir of iron, quinine, and strychnine phosphates was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the National Formulary, an official compendium, but its strength differed from or its quality or purity fell below the standard set forth therein, since it yielded less than 3.875 grams, namely, not more than 1.17 grams of the anhydrous alkaloids of quinine and strychnine per 1,000 cubic centimeters; whereas the National Formulary provides that elixir of iron, quinine, and strychnine phosphates shall contain 5 grams of quinine phosphate and 250 milligrams of strychnine phosphate per 1,000 cubic centimeters, and a drug so prepared should yield not less than 3.875 grams of the anhydrous alkaloids of quinine and strychnine per 1,000 cubic centimeters; and its difference in strength, quality, or purity from the standard set forth in said compendium was not stated plainly on the label. The article was alleged to be misbranded in that the statement "Elixir Iron, Quinine and Strychnine Phosphates N. F. VI.," borne on the label, was false and misleading since it did not comply with the specifications for elixir of iron, quinine, and strychnine phosphates set forth in the National Formulary, sixth edition.

The ammoniated mercury ointment was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from or its quality or purity fell below the standard set forth in that compendium, since it contained not more than 4.22 percent of ammoniated mercury; whereas the pharmacopoeia provides that ammoniated mercury ointment shall contain 10 percent of ammoniated mercury. It was alleged to be misbranded in that the statement, "Ammoniated Mercury Ointment * * * U. S. P. This ointment contains 10% Ammoniated Mercury U. S. P.," borne on the label, was false and misleading, since it did not comply with the specifications for ammoniated mercury set forth in the pharmacopoeia and it contained less than 10 percent of ammoniated mercury.

On February 10, 1941, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of $50 and costs.

349. Adulteration and misbranding of aromatic spirits of ammonia and larkspur lotion. U. S. v. Royal Manufacturing Co. of Duquesne, Koloman Kovacs, Samuel S. Kovacs, and Martin Kovacs. Pleas of nolo contendere. Judgment of guilty. Total fines, $400. Individual defendants placed on probation for 3 years. (F. D. C. No. 2078. Sample Nos. 77148–D, 77149–D.)

This case involved a shipment of a drug purporting to be aromatic spirits of ammonia but part of which was found to consist of larkspur lotion, and of a drug purporting to be larkspur lotion but a part of which was found to be spirits of ammonia.

On September 5, 1940, the United States attorney for the Western District of Pennsylvania filed an information against the Royal Manufacturing Co. of Duquesne, a corporation, Duquesne, Pa., and Koloman Kovacs, Samuel S. Kovacs, and Martin Kovacs, alleging shipment on or about October 11, 1939, from the State of Pennsylvania into the State of Virginia of quantities of spirits of ammonia and larkspur lotion which were adulterated and misbranded. The articles were labeled in part: "Powertay Spirits of Ammonia Aromatic [or

"Larkspur Lotion"] * * * Distributed by Powers-Taylor Drug Company, Richmond, Virginia."

The product purporting to be spirits of ammonia was alleged to be adulterated in that its strength differed from and its quality and purity fell below that which it purported or was represented to possess in that each of the bottles was represented to contain spirits of ammonia aromatic U. S. P.; whereas each of said bottles did not contain spirits of ammonia aromatic U. S. P. but a number of them did contain larkspur lotion. It was alleged to be adulterated further in that another substance, namely, larkspur lotion, had been substituted in part for spirits of ammonia aromatic U. S. P.

The product purporting to be spirits of ammonia was alleged to be misbranded in that the statements, "Spirit of Ammonia Aromatic U. S. P. Alcohol 65% By Vol. * * * An Agreeable stimulant and carminative preparation," borne on the label, were false and misleading in that they represented that the article consisted of aromatic spirits of ammonia which conformed to the requirements of the United States Pharmacopoeia, that it contained 65 percent of alcohol by volume and was an agreeable stimulant and carminative preparation; whereas it was not as represented in that the article in a number of bottles consisted of larkspur lotion, the larkspur lotion in the said bottles contained not more than 22.1 percent of alcohol by volume, and larkspur lotion is not an agreeable stimulant and carminative preparation. It was alleged to be misbranded further in that it consisted in part of larkspur lotion and was offered for sale under the name of another article, namely, "Spirits of Ammonia Aromatic U. S. P."

The product purporting to be larkspur lotion was alleged to be adulterated in that its strength differed from and its quality and purity fell below that which it purported and was represented to possess in that each bottle was represented to contain larkspur lotion; whereas a number of said bottles contained spirits of ammonia aromatic. It was alleged to be adulterated further in that another substance, namely, spirits of ammonia aromatic U. S. P. had been substituted in part for larkspur lotion.

The product purporting to be larkspur lotion was alleged to be misbranded in that the statement "Larkspur Lotion * * * Alcohol 20% by Vol.," borne on the bottle label, was false and misleading since it represented that the article consisted of larkspur lotion and contained 20 percent of alcohol by volume; whereas the article in a number of the bottles consisted of aromatic spirits of ammonia and the aromatic spirits of ammonia in the said bottles contained not less than 68.1 percent of alcohol. It was alleged to be misbranded further in that it consisted in part of aromatic spirits of ammonia and was offered for sale under the name of another article, namely, larkspur lotion.

On October 24, 1940, pleas of nolo contendere having been entered on behalf of each of the defendants, they were found guilty by the court. The corporation and each of the individual defendants were fined $100 and one-fourth of the costs on count I, and the individual defendants were placed on probation for 3 years on the remaining three counts.

350. Adulteration of tincture of digitalis. U. S. v. Yates Drug & Chemical Co. Tried to the court. Judgment for the Government. Fine, $500. (F. D. C. No. 940. Sample No. 68344–D.)

This product differed from the strength, quality, and purity set forth in the United States Pharmacopoeia for tincture of digitalis.

On July 30, 1940, the United States attorney for the Southern District of New York filed an information against the Yates Drug & Chemical Co., a corporation, New York, N. Y., alleging delivery for introduction in interstate commerce, namely, a delivery on or about September 18, 1939, for shipment from the State of New York into the State of New Jersey, of a quantity of tincture of digitalis that was adulterated.

The article was alleged to be adulterated in that its label bore the words "Tincture Digitalis U. S. P. XI," which purported and represented that it was a drug the name of which is recognized in an official compendium, namely, the United States Pharmacopoeia, eleventh edition, and that it was of the strength, quality, and purity of tincture of digitalis as set forth in said compendium; whereas its strength fell below the standard for strength of tincture of digitalis so set forth in this, that whereas the eleventh edition of the United States Pharmacopoeia states that the potency of tincture of digitalis shall be such that 1 cubic centimeter thereof shall possess an activity equivalent to not less than 1 and not more than 1.1 U. S. P. digitalis units, the potency of the article was such that 1 cubic centimeter possessed an activity equivalent to not more than 0.58 U. S. P.

digitalis units, and its label did not plainly state that the drug differed in strength from the standard of strength prescribed for such drug in such compendium.

On November 19, 1940, a jury having been waived, the case came on for trial before the court. Evidence was introduced on behalf of the defendant and by the Government, and on December 2, 1940, the court entered judgment for the Government, handing down the following opinion:

LEIBELL, *District Judge.* "Of course, a jury does not render any opinion, and I am sitting as a jury in this case, both sides having waived a trial by jury and consented to a trial by the court without a jury; the defendant on its part through a stipulation signed by one of its officers and by its counsel, and also the Government having signed the stipulation waiving the jury trial and consenting to this arrangement.

"I have given close attention to the evidence that was offered, and sitting as a court I have also asked a number of questions as the case went along. I realize, of course, that the burden is on the Government to establish the guilt of the defendant beyond a reasonable doubt. The court having charged what a reasonable doubt means in so many cases, I do not need to remind myself of it. I have reached the conclusion that the proof of the Government was most detailed both as to the preparation and use of the standard powder of digitalis and also the sale, delivery in interstate commerce, and the subsequent tests of the defendant's tincture of digitalis contained in this Exhibit 9.

"I have not any doubt that the tincture of digitalis sold by the defendant, as charged in the information, was substandard and that it did not exceed 60 percent of the standard required by the United States Pharmacopoeia, eleventh edition. A variance of some 20 percent from standard was allowed, but this is a variance of 40 percent. I believe that the test set forth in the United States Pharmacopoeia is definite, understandable, and readily followed by those whose business it is, with expert knowledge, to make those tests. I think the testimony of the experts here all shows that they knew how to go about making the tests required by the United States Pharmacopoeia for the preparation of the tincture of digitalis.

"The test prescribed in the pharmacopoeia is the one that under the law must be followed. It may be that at some future date more accurate tests will be developed. However, in this case it has been shown that the 1-hour frog method does produce a very accurate result when applied by different experts to the same sample of tincture of digitalis.

"It may be that the defendant when it sold the bottle of tincture of digitalis, which is the subject of this information filed against the defendant, believed that it complied with the standard required by law, but that is not the test that the law lays down. I do not question and have no reason to question the good faith of the defendant, and I have no reason to believe that a concern that has been in business 40 years would deliberately and wilfully sell this bottle of tincture of digitalis knowing that it was substandard, as the proof has shown here. But it is not necessary that the Government show under the statute that the sale was wilful and deliberate and with full knowledge of the substandard condition of the tincture of digitalis. I do not see what this defendant had to gain from selling the substandard tincture of digitalis, in a monetary way, considering the reputation of the defendant in its field as a manufacturing chemist, so that in finding the defendant guilty as charged in the information and, of course, subject to the imposition of a penalty under the provisions of the act, subject to the punishment provided in the act, I think it is only fair that I should state that there is not anything to show that the defendant deliberately set out to sell a substandard digitalis. In fact, the only proof as to the potency of the tincture of digitalis at the time that this particular batch was made up, namely, the testimony of Dr. Pearson, is to the effect that it was then standard tincture of digitalis. I think his percentage was around 94 percent, was it?"

Mr. KELLY. "Ninety-six percent."

THE COURT. "Ninety-six percent. But I have not any doubt at all but that the Government has shown that this particular tincture of digitalis sold by the defendant in interstate commerce was substandard in that it had a potency of less than 60 percent of the unit of potency required by the U. S. Pharmacopeia, which in turn is referred to in the statute itself, Section 351 (b), Title 21, U. S. code annotated, which is part of the Food and Drug Act.

"There is not any doubt either that the label on Exhibit 9 represented that this was tincture of digitalis of standard strength. When I say 'standard

strength' I mean the strength prescribed for the drug tincture of digitalis in the U. S. Pharmacopeia, eleventh edition. Now, just how this happened to be in a substandard condition, while that is immaterial on the question of the violation of the statute, it may have occurred through deterioration; it may have occurred in the packaging of it; it may have been the fault of some employee, or it may have been through an oversight or negligence. But I think all of that is outside the case, or the realm of proof in determining the guilt or innocence of this defendant, and the question involved is whether or not it was actually substandard and was sold by the defendant represented as standard and sold in interstate commerce.

"It is unfortunate, of course, that a concern which has been in business as long as the defendant, the Yates Drug & Chemical Co., should be found guilty of a violation of the Food and Drug Act, but, as I stated before, there is nothing to indicate that the violation was deliberate or undertaken for the sake of gain or profit for the defendant.

"So, sitting as both the court and jury in this case, I find the defendant, Yates Drug & Chemical Co., guilty as charged in the information.

"I will hear you on the question of the penalty, section 333. * * *

THE COURT. "Of course, the particular statute involved here is section 331 (a) the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

Mr. KELLY. "Yes, sir."

THE COURT. "The label represented that this tincture of digitalis was the U. S. P. XI and had been biologically tested so that it was supposed to comply with the U. S. P. XI as to potency, and the representation was that it did comply. Of course, then, there is this section 351 (b) relating to the strength or purity different from the official compendium which, of course, must be read together with section 331 as constituting the offense. Then we come to section 333 (a) which is just a straight violation, and the penalty may be imprisonment of not more than a year or a fine of not more than $1,000 or both. Of course, this defendant is a corporation. So, we have to consider the question of a fine. The penalty does not fall under section 333 (b) where intent to defraud or mislead is an essential element and the penalty accordingly higher. Well, of course, the Government has been put to a lot of proof. I think that you might have stipulated to some of it."

Mr. KELLY. "Well, I was not asked to do that, if your honor please."

THE COURT. "I know, but there was then this proof about the shipment in interstate commerce and also the actual use of a part of Exhibit 9 in making these tests by the Government."

Mr. BURLING. "If your honor please, I did not take it up with Mr. Kelly. I requested another attorney of Milbank, Tweed & Hope, who specifically declined to stipulate as to the interstate commerce shipment."

Mr. KELLY. "I think counsel is referring to the shipment in interstate commerce, is that it?"

THE COURT. "Yes."

Mr. BURLING. "Your honor, after that I made no request for stipulation, because Mr. O'Connell, who I believe was the party, told me that counsel for the defendant would stipulate as to nothing and, of course, I did not make further requests."

THE COURT. "Well, then, there was the question of the ampuls and they had to go through a lot of detailed proof as to the fact that what was used as the official test powder came from the proper source and all that, and I think a lot of that proof might have been saved. I suppose, of course, that a lot of the cross-examination of the Government witnesses as to the methods of the test and the proper testimony of experts for the defendant was to be expected.

"Under all the circumstances, I am of the opinion that the sentence of the court in this case should be that the defendant, Yates Drug & Chemical Co., shall pay a fine of $500.

"Well now, the case is completed and, of course, it is a case that has been one of great interest to follow, and the attorneys on both sides have presented their respective proofs and arguments showing great care in preparation, and conducted themselves throughout the trial as attorneys who knew how to go about the work of trying their case and had a proper respect not merely for the court but for each other, which is a delightful thing to see in any case, lawyers having respect for each other. It has been a pleasure to have you both here."

The defendant was sentenced to pay a fine of $500.

SEIZURES

351. Adulteration of epinephrine chloride solution. U. S. v. 12 Bottles of Epinephrine Chloride Solution. Default decree of condemnation and destruction. (F. D. C. No. 2408. Sample Nos. 15179–E, 15266–E.)

This product had been shipped in interstate commerce and was in interstate commerce at the time of examination, at which time it was found that it did not conform to the requirements of the United States Pharmacopoeia.

On July 23, 1940, the United States attorney for the Southern District of Iowa filed a libel against 12 bottles of epinephrine chloride solution at Des Moines, Iowa, alleging that the article had been shipped in interstate commerce on or about January 18, 1937, by the Difco Laboratories, Inc., from Detroit, Mich.; and charging that it was adulterated.

It was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, but its quality fell below the standard set forth in the pharmacopoeia since examination showed that it was dark brown in color and contained sediment; whereas epinephrine chloride solution is a synonym for a solution of epinephrine hydrochloride, a designation used by the United States Pharmacopoeia, which states that a solution of epinephrine hydrochloride is "a nearly colorless * * * liquid, gradually turning dark on exposure to air and light, and when the solution has become brown in color, or contains a precipitate, it must be rejected."

On October 9, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

352. Adulteration of mineral oil. U. S. v. 16 Drums of White Oil. Decree of condemnation. Product released under bond to be disposed of for technical purposes. (F. D. C. No. 2550. Sample No. 14969–E.)

This product fell below the pharmacopoeial specifications because of the presence of moisture and solid paraffins.

On August 13, 1940, the United States attorney for the Eastern District of Pennsylvania filed a libel against 16 drums of white oil at Philadelphia, Pa., alleging that the article had been shipped in interstate commerce on or about July 30, 1940, by the Wanango Oil Corporation from Newark, N. J.; and charging that it was adulterated in that it purported to be or was represented as a drug the name of which is recognized in an official compendium, but its strength differed from and its quality and purity fell below the standard set forth in such compendium. It was labeled in part "White Oil."

On September 9, 1940, the American Oil & Supply Co., Newark, N. J., having appeared as claimant, judgment of condemnation was entered and the product was ordered released under bond. On September 21, 1940, the decree was amended to provide that the product should not be disposed of except for technical purposes in the manufacture of various compounds.

353. Misbranding of mineral oil. U. S. v. 1,409 Dozen Pints of Mineral Oil. Consent decree of condemnation. Product released under bond for relabeling. (F. D. C. No. 3218. Sample No. 30199–E.)

This product was light mineral oil. It was in interstate commerce when examined, at which time it was found to be labeled to indicate that it was heavy mineral oil.

On or about October 23, 1940, the United States attorney for the Northern District of Illinois filed a libel against 1,409 dozen pint bottles of mineral oil at Chicago, Ill., alleging that the article had been shipped in interstate commerce on or about August 21, 1940, by the Atlantic Refining Co. from Point Breeze, Philadelphia, Pa., and consigned to Walgreen Drug Stores, Chicago, Ill. The product, when shipped in interstate commerce, was in bulk and had been invoiced by the shipper as "1 Tank Car Atreol 13 White Mineral Oil USP Light." Upon arrival at Chicago it was put up in pint bottles and was incorrectly labeled in part: "White Mineral Oil (USP Light) Russian Type * * * Union Drug Co., Distributor, Chicago, Illinois."

The libel alleged that the said oil so labeled was misbranded in that the statement "Russian Type," was false and misleading as applied to a light white mineral oil of domestic origin.

On December 2, 1940, the Walgreen Co., Chicago, Ill., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be properly relabeled under the supervision of the Food and Drug Administration.

354. Adulteration and misbranding of halibut liver oil capsules. U. S. v. 24,000, 75,000, and 90,000 Halibut Liver Oil Capsules. Consent decrees of condemnation. Product ordered released under bond for relabeling. (F. D. C. Nos. 2051, 2052, 2054. Sample Nos. 33424–E, 33425–E, 33426–E.)

This product was represented to consist of halibut liver oil but consisted in part of other fish-liver oil.

On June 1 and 3, 1940, the United States attorneys for the Southern District of New York and the Eastern District of New York filed libels against a total of 99,000 halibut liver oil capsules at New York, N. Y., and 90,000 halibut liver oil capsules at Brooklyn, N. Y., alleging that the article had been shipped in interstate commerce within the period from on or about October 5, 1939, to on or about February 14, 1940, by the White Laboratories, Inc., from Newark, N. J.; and charging that it was adulterated and that portions were also misbranded. Portions were labeled in part: "Halibut Liver Oil Capsules * * * Halibut Plain," or "Halibut Liver Oil Pl."

All lots of the article were alleged to be adulterated in that another fish-liver oil had been wholly or in part substituted for plain halibut-liver oil. All lots were alleged to be misbranded in that they were offered for sale under the name of another drug. Portions were alleged to be misbranded further in that the statements, "Halibut Liver Oil * * * Capsules," "Halibut Liver Oil Plain," and "Halibut Liver Oil Pl.," were false and misleading, since the article did not consist of halibut liver oil but was a mixture of fish-liver oils.

On June 25, 1940, White Laboratories, Inc., claimant, having admitted the allegations of the libels, judgments of condemnation were entered, and it was ordered that the product be released under bond conditioned that it be relabeled so as to declare that the capsules contained halibut-liver oil which had been mixed with another fish oil.

355. Adulteration and misbranding of Estrinol in oil. U. S. v. 118 Ampuls of Estrinol in Oil. Default decree of condemnation and destruction. (F. D. C. No. 2500. Sample No. 3064–E.)

Each cubic centimeter of this product was represented to possess an activity equivalent to 5,000 International Units of estrogenic substance, whereas it was inert.

On August 7, 1940, the United States attorney for the Western District of Pennsylvania filed a libel against 118 ampuls of Estrinol in oil at Pittsburgh, Pa., alleging that the article had been shipped in interstate commerce on or about March 8, 1940, by the Bellevue Laboratories, Inc., from New York, N. Y.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely: (Label) "1 CC is therapeutically equivalent to 5,000 I. U. of estrogenic substance." It was alleged to be misbranded in that the statement on the label, "1 CC is therapeutically equivalent to 5,000 I. U. of estrogenic substance," was false and misleading as applied to an article which was inert.

On September 25, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

356. Adulteration and misbranding of Shores Ka-Vi-Min Tablets. U. S. v. 1⅔ Drums Containing 71,300 Tablets of Shores Ka-Vi-Min Tablets. Default decree of condemnation and destruction. (F. D. C. No. 3992. Sample No. 32805–E.)

This product was labeled as containing 140 U. S. P. units of vitamin D and 25 International Units of vitamin B_1 per tablet; whereas it contained not more than 100 U. S. P. units of vitamin D and not more than 15 U. S. P. units of vitamin B_1 (1 U. S. P. unit of vitamin B_1 is equal to 1 International Unit of the same vitamin).

On March 14, 1941, the United States attorney for the Southern District of California filed a libel against 1⅔ drums of Shores Ka-Vi-Min Tablets at Los Angeles, Calif., alleging that the article had been shipped in interstate commerce on or about February 28, 1940, by the Shores Co. from Cedar Rapids, Iowa; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess. It was alleged to be misbranded in that the following statements were false and misleading, since each tablet did not contain 140 U. S. P. units of vitamin D or 25 International Units of vitamin B_1: "Each tablet contains * * * 140 USP units Vitamin D" and "25 International units Vitamin B_1." The article was also

charged to be adulterated and misbranded under the provisions of the law applicable to food, as reported in notices of judgment on foods.

On April 14, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

357. Adulteration and misbranding of Sea-Clo-400-D. U. S. v. 4 Cans of Sea-Clo-400-D. Default decree of condemnation and destruction. (F. D. C. No. 1611. Sample No. 78465-D.)

This veterinary product contained not more than 200 A. O. A. C. chick units of vitamin D per gram and contained less than 500 U. S. P. units of vitamin A; whereas it was represented in the labeling that it contained 400 A. O. A C. units of vitamin D per gram and that it contained substantially 1,000 units of vitamin A per gram.

On March 14, 1940, the United States attorney for the Northern District of West Virginia filed a libel against 4 50-pound cans of Sea-Clo-400-D at Martinsburg, W. Va., alleging that the article had been shipped in interstate commerce on or about January 2, 1940, by Sea Board Supply Co., Inc., from Philadelphia, Pa.; and charging that it was adulterated and misbranded. It was labeled in part: "Sea-Clo-400-D Highly Fortified Cod Liver Oil in Dry Base."

The article was alleged to be adulterated in that its strength differed from and its purity fell below that which it purported or was represented to possess, that is, it was labeled: "Guaranteed to contain 400 A. O. A. C. units of Vitamin D per gram. When this product is packed it contains more than 1000 Units of Vitamin 'A' per gram, but due to a difference of opinion of our many Authorities regarding the stability of Vitamin 'A' from Cod Liver Oil when added to feeds, we are making no claim for it."

It was alleged to be misbranded in that the following statements appearing on the label were false and misleading: "Sea-Clo-400-D * * * In place of each 4¾ lbs. straight 85-D Oil, use 1 lb. Sea-Clo-400-D. In place of each 1 lb. Fortified 400-D Oil, use 1 lb. Sea-Clo-400-D. For each 5 pints 85-D Oil used, replace with 1 lb. Sea-Clo-400-D."

On November 27, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING THERAPEUTIC CLAIMS

DRUGS ALSO FAILING TO BEAR COMMON OR USUAL NAME OR REQUIRED INGREDIENT STATEMENT

358. Misbranding of Alpine Tea. U. S. v. 57 Packages of Alpine Tea. Default decree of condemnation and destruction. (F. D. C. No. 3219. Sample No. 26435-E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated below. The statement of analysis on the label was misleading since it represented the analysis of the ash and not of the tea itself. Its label also failed to bear a statement of its common name.

On October 21, 1940, the United States attorney for the District of Oregon filed a libel against 57 packages of Alpine Tea at Rainier, Oreg., alleging that the article had been shipped in interstate commerce by the Alpine Tea Co. on or about September 2, 1939, from Detroit, Mich.; and charging that it was misbranded.

Analysis showed that the article consisted of cut dried leaves of blueberry.

The article was alleged to be misbranded in that representations in the labeling that it would be efficacious to balance the deficiency of body minerals; stimulate the pancreatic glands, kidneys, bladder, and liver; increase vitality amazingly and almost immediately, which increase would continue throughout the day; would help one get a good night's rest; would serve as an effective aid to the diabetic's diet, and would decrease the need for insulin; and that it was not only efficacious for diabetics but was also good for other ailments such as those of the liver, spleen, kidneys, bladder, and for stomach ulcers, were false and misleading since it would not be efficacious for such purposes.

It was alleged to be misbranded further in that the following statements in the labeling, (carton) "Analysis: Silica (SiO_2) 10.99%; Iron Oxide (Fe_2O_3) 1.90%; Manganese Oxide (Mn_3O_4) 5.10%; Aluminum Oxide (Al_2O_3) 11.38%; Calcium Oxide (CaO) 21.84%; Magnesium Oxide (MgO) 7.27%; Sodium Na (as Na_2O) 7.11%; Potassium K (as K_2O) 10.06%; Sulphate (SO_3) 5.32%; Phosphate (P_2O_5) 5.86%; Carbonate (60_2) 10.17%; Chloride (Cl) 2.00%; Free

Carbon, Charcoal, etc. 2.00%; Potassium calculated as carbonate 14.76%; Copper, Tin, Lead, Arsenic, Mercury, None," were false and misleading since they did not represent an analysis of the product itself. It was alleged to be misbranded further in that its label failed to bear its common or usual name.

On November 17, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

359. Misbranding of Ancestral Oil. U. S. v. 33 Packages of Ancestral Oil. Default decree of condemnation and destruction. (F. D. C. No. 2461. Sample No. 16067–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter. Its labeling also failed to bear an accurate statement of the quantity of the contents and the common or usual names of the active ingredients. The product was also deceptively packaged. It was packed in a thick-walled panel bottle with rather a long neck which was contained in a carton, creating the impression that a larger volume of the liquid was furnished than was actually the case.

On or about August 6, 1940, the United States attorney for the Western District of Missouri filed a libel against 33 packages of Ancestral Oil at Kansas City, Mo., alleging that the article had been shipped in interstate commerce on or about April 26, 1940, by the Ancestral Medicine Co. from Osawatomie, Kans.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of a fish oil and turpentine.

The article was alleged to be misbranded in that the labeling bore representations that it was efficacious in the treatment of piles, rheumatism, hay fever, lumbago, earache, coughs, asthma, kidney affections, croup, whooping cough, influenza, dysentery, and bloody diarrhea, phthisis, pneumonia, bronchitis and sore throat, for inflammation of the breasts, neuralgia, lumbago, soreness of corns and bunions, toothache, vaginal discharge or ulcers, diphtheria, lung troubles, burn or scald, cuts, bruises, or sprains, that it would not blister or irritate the tenderest skin; that it would penetrate, heal, and cure; that it was efficacious for the kidneys; would allay various forms of inflammation and pleurisy; would cut phlegm, prevent a scar; that it was the most beneficial remedy for all ailments the human family was heir to; that it was the best all-purpose remedy for garget or caked udder, inflammation of the udder, and that it was excellent for horses and would be efficacious in the treatment of all flesh wounds, which representations were false and misleading since the article would not be efficacious for such purposes. It was alleged to be misbranded further in that the label did not bear an accurate statement of the quantity of the contents and did not bear the common or usual name of the active ingredients. It was alleged to be misbranded further in that the containers were so made, formed, or filled as to be misleading.

On November 25, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

360. Adulteration and misbranding of Edwenil. U. S. v. 15 Boxes, et al., of Edwenil. Default decree of condemnation and destruction. (F. D. C. No. 1843. Sample Nos. 10346–E to 10349–E, incl.)

This product would not activate or fortify the natural defenses of the body as represented and suggested in the labeling.

On April 24, 1940, the United States attorney for the Southern District of New York filed a libel against 15 boxes each containing 10 4-cc. vials of Edwinil; 35 boxes each containing 5 4-cc. vials of Edwenil; 10 boxes each containing 10 10-cc. vials of Edwenil; and 79 boxes each containing 1 10-cc. vial of Edwenil at New York, N. Y., alleging that the article had been shipped in interstate commerce within the period from on or about February 21 to on or about April 2, 1940, by Spicer & Co. from Glendale, Calif.; and charging that it was adulterated and misbranded.

Analysis showed that the article consisted of a colorless liquid carrying suspended amorphous white material containing total solids (approximately 1.0 percent) chiefly sodium chloride (approximately 0.8 percent) and suspended matter (0.1 percent), chiefly silicates and phosphates, and nitrogenous matter (approximately 0.03 percent), and water.

The article was alleged to be adulterated in that it was represented to possess a strength and quality sufficient to activate and fortify the natural defenses of the body against acute and chronic endotoxic infections when administered in specified doses; whereas it did not possess the strength or quality to activate

and fortify the natural defenses of the body against acute and chronic endotoxic infections when so administered.

It was alleged to be misbranded in that representations in the labeling that it would be efficacious in the treatment of infections of the endotoxic type by activating the natural defenses were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further in that it was offered for sale under the name of another drug, namely, under the name previously given to an article containing substantially different ingredients and intended for use in the cure, mitigation, treatment, or prevention of disease in man.

The article, with the exception of that contained in 8 boxes each containing 10 10-cc. vials, was alleged to be misbranded further in that the label failed to bear the common or usual name of each active ingredient.

On October 7, 1940, the case having been called and the claimant having failed to appear or answer, judgment of condemnation was entered and the product was ordered destroyed.

361. Misbranding of World's Tonic Compound with Alkalines. U. S. v. 64 Packages of World's Tonic Compound with Alkalines. Default decree of condemnation and destruction. (F. D. C. No. 2672. Sample No. 27270–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter, and it also failed to bear an accurate statement of the quantity or proportion of strychnine present.

On August 28, 1940, the United States attorney for the Northern District of West Virginia filed a libel against 64 packages of the above-named product at Parkersburg, W. Va., alleging that the article had been shipped in interstate commerce on or about July 6, 1940, by the World's Medicine Co. from Columbus, Ohio; and charging that it was misbranded.

Analysis showed that the article consisted essentially of extracts of plant drugs including sassafras, licorice, and laxative plant drugs such as aloe and emodin-bearing drugs, together with alcohol (12 percent), a small quantity of iron, strychnine (not over 0.004 grain per fluid ounce, equivalent to 0.36 grain of nux vomica), and a very small proportion of alkaline substances.

It was alleged to be misbranded in that the following and similar statements appearing in the labeling were false and misleading since it was essentially a laxative and could not serve as a tonic or as a source of alkalies: (Carton, bottle, and circular) "World's Tonic Compound With Alkalines"; (circular) "Contains a combination of especially selected herbs, barks and roots, vegetable in origin and recognized for their merit. All Roots, Barks, Herbs, etc., used in World's Tonic and imported from Foreign Countries are Examined by the United States Department of Agriculture. * * * The number of bottles of World's Tonic Compound with alkalines one should take to bring about the best results varies according to the condition of the person." It was alleged to be misbranded further in that the label did not bear a statement of the quantity or proportion of strychnine since the statements "Nux Vomica 3 grains to each fluid ounce, containing 1.15% of a grain of strychnine to each grain of nux vomica," borne on the label, was incorrect.

On January 7, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

362. Misbranding of hair tonic. U. S. v. 72 Pint Bottles of Red Fox Quinine Hair Tonic. Default decree of condemnation and destruction. (F. D. C. No. 3621. Sample No. 20735–E.)

The labels of this product failed to bear a statement of the active ingredients and an accurate statement of the quantity of the contents, and some failed to bear a statement of the quantity or proportion of alcohol. Moreover, it would not be efficacious as a hair tonic as represented on the labels, nor would it be efficacious for the relief of dandruff as represented on some of the labels.

On January 2, 1941, the United States attorney for the Southern District of Florida filed a libel against 72 pint bottles of Red Fox Quinine Hair Tonic at Jacksonville, Fla., alleging that the article had been shipped in interstate commerce from Brooklyn, N. Y., by the Healox Co., Inc., on or about November 12, 1940; and charging that it was misbranded.

Analysis showed that it consisted essentially of alcohol, water, and small amounts of brucine and perfume material. It contained no quinine.

The article was alleged to be misbranded in that the statements "Quinine Hair Tonic" on all the labels, and "Relieves Dandruff," appearing on some of the

labels were false and misleading, since it was not efficacious for the purposes recommended.

It was alleged to be misbranded further in that its label did not bear an accurate statement of the quantity of the contents; and in that the label did not bear the common or usual names of the active ingredients, and some of the labels did not bear a statement of the quantity or proportion of alcohol that it contained.

On March 11, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

363. Misbranding of Wonder Dandruff Cure. U. S. v. 69 Bottles of Wonder Dandruff Cure. Default decree of condemnation and destruction. (F. D. C. No. 3721. Sample No. 52198–E.)

The label of this product contained false and misleading representations regarding its efficacy in the conditions indicated below. It also failed to bear a statement of the quantity and proportion of alcohol and arsenic and an accurate statement of the quantity of contents.

On January 29, 1941, the United States attorney for the District of Oregon filed a libel against 69 bottles of Wonder Dandruff Cure at Eugene, Oreg., alleging that the article had been shipped on or about August 3, 1940, by the Wonder Dandruff Cure Co. from Cedar Rapids, Iowa; and charging that it was misbranded.

Analysis of a sample of the article showed that it was an artificially colored, perfumed aqueous fluid containing arsenic, alcohol, and glycerin.

The article was alleged to be misbranded in that the following statements appearing in the labeling were false and misleading since it was not efficacious for the purposes recommended: "Wonder Dandruff Cure * * * positively eradicates dandruff, restores lifeless hair to a healthy natural condition and prevents it from coming out, stops irritation and itching of the scalp. The Wonder Dandruff Cure Company. Apply to scalp with fingers not more than three times a week until dandruff disappears."

It was alleged to be misbranded further in that the label did not bear the common or usual name of each active ingredient, an accurate statement of the quantity and proportion of alcohol, nor the quantity or proportion of arsenic or any derivative or preparation of arsenic.

On March 11, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

364. Misbranding of Marie de Medicis Scalp Food. U. S. v. 9½ Dozen Retail Packages of Marie de Medicis Scalp Food. Default decree of condemnation and destruction. (F. D. C. No. 3976. Sample No. 28151–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On March 14, 1941, the United States attorney for the District of Maryland filed a libel against 9½ dozen retail packages of Marie de Medicis Scalp Food at Baltimore, Md., alleging that the article had been shipped in interstate commerce on or about September 30, 1940, from Philadelphia, Pa., by Marie de Medicis Products Co.; and charging that it was misbranded.

Analysis showed that the article consisted of a perfumed brown ointment containing free sulfur, lanolin, and petrolatum.

The article was alleged to be misbranded in that representations in the labeling regarding its efficacy to make the hair beautiful and healthy, to nourish the scalp, to loosen a dry scalp; and its efficacy in the treatment of dandruff, falling hair, itching scalp, and various scalp ills, were false and misleading since it was not efficacious for the purposes recommended. It was alleged to be misbranded further in that it was fabricated from two or more ingredients and the label did not bear the common or usual name of each active ingredient.

On April 16, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

365. Misbranding of Iodimelk. U. S. v. 151½ Gallons of Iodimelk. Consent decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 2400. Sample No. 4526–E.)

The labeling of this veterinary product contained false and misleading representations regarding its efficacy in the conditions indicated below, and it also failed to bear certain information required by law.

On or about July 26, 1940, the United States attorney for the Northern District of Illinois filed a libel against 151½ gallons of Iodimelk at Chicago, Ill., alleging that the article had been shipped in interstate commerce on or about June 8,

1940, by the Dawes Products Co. from Denver, Colo.; and charging that it was misbranded.

Analysis showed that it consisted essentially of concentrated buttermilk and combined iodine.

The article was alleged to be misbranded in that the following statements in the labeling were false and misleading since they represented that it was efficacious for the purposes recommended; whereas it was not efficacious for such purposes: "Digestive Tract Control of Cocci * * * An Aid in Control of Coccidiosis Blackhead in Poultry Ducks Turkeys Game Fowls." It was alleged to be misbranded further in that the label failed to bear an accurate statement of the quantity of contents; in that the label failed to bear the name and address of the manufacturer, packer, or distributor; and in that it failed to bear the common or usual names of the active ingredients of the article.

On September 6, 1940, the Dawes Products Co., claimant, having admitted the allegations of the libel and having consented to the entry of a decree, judgment of condemnation was entered and it was ordered that the product be released under bond for relabeling under the supervision of the Food and Drug Administration.

366. Misbranding of Ko-Ex-7 Powder and Ko-Ex-7 Mastitis Detector. U. S. v. 11 Packages of Ko-Ex-7 Powder and 11 Packages of Ko-Ex-7 Mastitis Detector. Default decrees of condemnation and destruction. (F. D. C. Nos. 2250, 2251. Sample Nos. 3665–E, 3666–E.)

The labeling of these veterinary products bore false and misleading representations regarding their efficacy in the conditions indicated hereinafter. The label of the Mastitis Detector failed to bear the common or usual name of the active ingredient, namely, bromthymol blue.

On June 25, 1940, the United States attorney for the Western District of Pennsylvania filed libels against 11 16-ounce packages of Ko-Ex-7 Powder and 11 packages of Ko-Ex-7 Mastitis Detector at Meadville, Pa., alleging that the articles had been shipped in interstate commerce on or about May 3, 1940, by the Sunset Feed & Grain Co., Inc., from Buffalo, N. Y.; and charging that they were misbranded.

Analysis showed that the Ko-Ex-7 Powder consisted essentially of potassium nitrate, ferrous sulfate, boric acid, together with small proportions of ammonia and plant material; and that the Ko-Ex-7 Mastitis Detector consisted of a square of blotting paper, a portion of which had been impregnated with an indicator such as bromthymol blue, the purpose of which was to determine whether a solution placed thereon was acid or alkaline in reaction.

The mastitis detector was alleged to be misbranded in that the following statements in the labeling were false and misleading: "To stop losses from Mastitis—Use the Ko-Ex-7 Mastitis Detector * * * If detector shows milk derangement segregate cow at once, and begin treatment." It was alleged to be misbranded further in that the label failed to bear the common or usual name of the active ingredient.

The Ko-Ex-7 Powder was alleged to be misbranded in that representations in the labeling that it was efficacious in the treatment of mastitis, or garget, that it would help correct faulty metabolism, that it would bring about normal milk secretion, that it would be efficacious to control mastitis and stop mastitis losses, were false and misleading since it would not be efficacious for such purposes.

On July 30, 1940, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

CRIMINAL PROSECUTIONS

367. Misbranding of Axine Plates. U. S. v. Walter Gordon Pervis. Tried to the court and a jury. Verdict of guilty. Defendant sentenced to 6 months in jail and $1,000 fine. Jail sentence suspended and defendant placed on probation for 2 years. (F. D. C. No. 958. Sample No. 72023–D.)

The labeling of this device bore false and misleading representations and designs regarding its efficacy in the conditions indicated below.

On June 1, 1940, the United States attorney for the Middle District of Georgia filed an information against Walter Gordon Pervis, of Tennille, Ga., alleging shipment on or about September 30, 1939, from the State of Georgia into the State of Missouri of a quantity of Axine Plates which were misbranded. Accompanying the article was a circular headed "Health Without Medicine" which bore a design showing two individuals, one an invalid on crutches opposite whom was a figure purporting to be the same individual but healthy and vigorous. Emanating from the heels of the healthy individual were radiations indicating

electrical energy. Underneath the design were the words "Vigor" and "Produced by Electricity in the Human Body."

Examination showed that the article consisted of two plates, of which one consisted essentially of copper and the other consisted essentially of zinc.

The article was alleged to be misbranded in that the above-described design and certain statements in the circular represented that it would produce health and vigor by means of electricity in the human body; would relieve the stiffness of old age and make one feel young again; would rid the blood of uric acid; would be efficacious in the mitigation, treatment, and prevention of high blood pressure, low blood pressure, headache, asthma, paralysis, kidney trouble, rheumatism and diabetes, eczema, cold hands and feet, poor circulation; and would be efficacious "to draw the acid from the larynx glands and thus stop excessive coughing of asthma," were false and misleading since the article would not be efficacious for such purposes. The article was alleged to be misbranded further in that certain statements in the circular were false and misleading since they represented that uric acid forms in the stomach; that it forms as the result of eating food that disagrees with the stomach; that the acid then filters through the blood and travels through the blood as a very fine crystal; that the device consisted of a composition of metals which "would act upon the human electricity, and would make human electricity fast"; that it would heat the blood about 2 degrees, and thus dissolve uric acid in the blood; that uric acid would pass through the blood into the device, i. e., metal plates worn in the heels of the shoes; whereas uric acid does not form in the stomach, it does not form as the result of eating food that disagrees with the stomach; it does not filter through the blood and travel through the blood as a very fine crystal; the device would not act upon human electricity, and would not make human electricity fast; it would not heat the blood about 2 degrees, and would not dissolve uric acid in the blood; and uric acid would not pass through the blood into the device. The article was alleged to be misbranded further in that certain statements in the circular represented that the cause of high blood pressure is the uric acid crystals stopping in the arteries, hardening the arteries and enlarging the heart; that the device would stimulate one's own electric current; that the electric current would pass through the brain and dissolve and draw away clot on the brain caused by high blood pressure; whereas the cause of high blood pressure is not uric acid crystals stopping in the arteries, hardening the arteries and enlarging the heart; the device would not stimulate one's own electric current; and the electric current would not pass through the brain and dissolve and draw away the clot on the brain caused by high blood pressure. It was alleged to be misbranded further in that certain statements in the labeling represented that uric acid stiffens the prostate gland; that because of uric acid the prostate gland stands open and will not "pan down"; that failure of the prostate glands to "pan down" causes diabetes; that the device would produce heat by the metals acting as a battery on the human electricity; that the heat produced by the device would cause the prostate gland to "pan down" and relieve the patient, which representations were entirely false and misleading, since uric acid does not stiffen the prostate gland and cause it to stand open and fail to "pan down"; the failure of the prostate gland to "pan down" does not cause diabetes; the device would not produce heat by the metals acting as a battery on the human electricity; and it would not cause the prostate gland to "pan down" and relieve the patient entirely.

On November 11, 1940, a plea of not guilty having been entered, the case came on for trial before the court and jury. The trial was concluded on November 13, 1940, on which date the court delivered the following instructions to the jury:

DEAVER, *Judge:* "Gentlemen of the Jury. Without attempting to state to you all the provisions of the Food and Drug Act, it is only necessary for me to state one provision of it, and that is very short and simple. Congress has made it a crime to ship in interstate commerce, that is to say from one State into another State, any device which is misbranded. Now, misbranded under the terms of the statute is this: A device is misbranded when the label and statements in connection with it are false or misleading. That is the whole provision of the law applicable to this case.

"Now, the information in this case, which you will have out with you, is somewhat long but it charges in substance that this defendant shipped in interstate commerce a certain device, which you already know about, certain heel

plates known as Axine Plates, from this State into another State, and that the shipment was misbranded, that the device was misbranded; that is to say, that the statements or representations on the label or these circulars, which you have seen here in evidence and which you will have out with you, are false or misleading. Now, that is the question that you are to determine, whether the label or statements in connection with this device are false or misleading.

"Now, you will find in this indictment set out, I take it—I haven't read it but I think that you will find that true, you may read it all if you care to—the statements which were either on the label or in these circulars and the allegations in the information that certain things in here are false or misleading, and you will follow that right straight on through. It sets out one provision after another and then alleges that those statements are false or misleading in certain respects.

"Now, to that charge the defendant has entered on the back of this information a plea of not guilty. That plea is in substance a denial of every essential allegation in the information, and the information together with the plea of not guilty makes up an issue of fact, a question of fact, for this jury to determine.

"Then, the trial begins and the burden is on the Government to produce evidence sufficient to convince the jury beyond a reasonable doubt that the defendant is guilty, as charged.

"In the beginning of the trial, the defendant is presumed to be innocent and that presumption continues unless it is overcome by the testimony in the case, testimony sufficient to overcome the presumption and to convince the jury beyond a reasonable doubt that the defendant is guilty.

"The testimony has been somewhat long, necessarily long. There is no criticism of anybody in that connection because it was necessary to bring you the evidence bearing on this question and you are to take all of that evidence on both sides and consider all of it, oral testimony and documentary testimony, and say from it all what you honestly believe about it, what your honest conviction is as to whether the statements made by the defendant in these circulars or printed matter sent out with the shipment are false or misleading. If those statements are false and misleading, then the shipment was misbranded and, therefore, the shipping constituted a crime.

"That is all there is to the case. I say there is a lot of testimony but the question to be decided is very simple and easy to state.

"Now, I might just repeat it this one time: You determine from all the evidence in the case whether the statements made by this defendant in connection with the shipment of these heel plates are false or misleading. Oh, of course, there are a great many facts set out here in the information that are necessary with reference to jurisdiction and shipment in interstate commerce and various things of that sort, but, as you have heard here in the trial of this case, there is really no dispute between the parties here as to any of those things, and that's the reason why I say you haven't got but one question. It is admitted, I believe, here that the shipments were made in interstate commerce, that they contained these circulars and these representations and all those various things, and for that reason I say you have, in substance, only the one question to decide: Were these statements false or misleading? If they were, then he is guilty. If they were not, or if the Government has failed to convince you beyond a reasonable doubt that they are, then you ought to turn the defendant loose.

"You will write your verdict on the back of this information. There is a blank verdict there that you can fill out and let your foreman sign it, date it, and, if you think under all this testimony that the statements and representations made are false or misleading, then you ought to find this verdict, 'We the jury find the defendant guilty.' If you think the Government has failed to carry the burden of showing that fact, then your verdict ought to be, 'We the jury find the defendant not guilty.'"

Mr. Davis. "Your Honor, will you charge the jury that if they find that any of the statements are false, they should find the defendant guilty? There are quite a number of statements on there. They wouldn't have to find all of them were false."

"Yes, any of the statements, gentlemen of the jury, which in this information are alleged to be false or misleading. It wouldn't be necessary to prove that every statement in the circular or every statement set out in the copy of the circulars or representations in this information is false or misleading, but it is necessary to find, in order for you to find the defendant guilty, that some statement copied in this information and alleged to be false or misleading is false or misleading."

The jury retired and after due deliberation returned a verdict of guilty, and the court sentenced the defendant to 6 months in jail and imposed a fine of $1,000. On December 12, 1940, the court suspended the 6-months' jail sentence and placed the defendant on probation for 2 years.

368. Misbranding of Dr. Burnham's San-Yak K-L-B Pills. U. S. v. Robert H. Lee (Lee Chemical Co.). Plea of guilty. Sentence: 6 months' imprisonment which was suspended and defendant placed on probation for 2 years. Fine of $100 also imposed. (F. D. C. No. 2106. Sample No. 5761–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated below and falsely represented that it complied with the law.

On September 5, 1940, the United States attorney for the Eastern District of Michigan filed an information against Robert H. Lee, trading as Lee Chemical Co. at Birmingham, Mich., alleging shipment on or about March 15, 1940, from the State of Michigan into the State of Indiana of a quantity of the above-named product which was misbranded.

Analysis showed that the article contained extracts of plant drugs including cinchona, sandalwood, and a laxative drug, and compounds of magnesium, calcium, and iron.

The article was alleged to be misbranded in that representations in the labeling that it would be efficacious in establishing proper functioning of the kidneys and liver; that it would be beneficial in correcting rheumatism, sugar in the blood and high blood pressure; that it was an efficacious treatment and remedy for kidney, liver, and bladder disorders; that it would reduce sugar in the blood and urine, would relieve frequent urination, would alleviate aches and pains in the back and joints, and was efficacious in the treatment of constipation and piles; and that "each and all of the 15 ingredients used in the composition of the article were not misbranded within the meaning of the Pure Food and Drug Act," were false and misleading since the article would not be efficacious for the purposes claimed and was misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On November 29, 1940, a plea of guilty having been entered, the court imposed a fine of $100 and sentenced the defendant to 6 months' imprisonment, which sentence was suspended for a period of 2 years and the defendant was placed on probation for the same period.

369. Misbranding of Double Quick Liver Tablets, Compound Herb Tea, Blessed Herb Tea, Herb Wash, and St. Bernard Compound Herb Tea. U. S. v. Dr. Lyncha A. Johnson. Plea of guilty. Fine, $1,500. Sentenced to 6 months' imprisonment in a jail or a Federal prison camp. (F. D. C. No. 2112. Sample Nos. 84175–D to 84183–D, incl., 84380–D, 84641–D, 84642–D, 84645–D to 84647–D, incl.)

These products were misbranded because of false and misleading representations in the labeling regarding their efficacy in the treatment of the ailments for which they were recommended; false and misleading representations regarding the efficacy of herbs in the treatment of a great number of ailments, including the most serious disorders; and in some instances because of false and misleading representations regarding their ingredients.

On October 8, 1940, the United States attorney for the Western District of Tennessee filed an information against Dr. Lyncha A. Johnson, trading as Dr. Lyncha A. Johnson, at Memphis, Tenn., alleging shipment within the period from on or about January 4 to on or about January 16, 1940, from the State of Tennessee into the States of Arkansas and Missouri of quantities of the above-named proprietary herb remedies that were misbranded.

Analyses of samples of each of the four shipments of Double Quick Liver Tablets showed the following facts: (1) tablets contained plant materials, including ginger and emodin-bearing drugs such as senna, aloe, and podophyllum; (2) tablets contained plant material, including aloe, podophyllum, emodin-bearing drugs such as senna and buckthorn, and calomel (slightly less than 1 grain per tablet); (3 and 4) tablets consisted essentially of plant material (including ginger, podophyllum, and a laxative plant drug such as senna), and unidentified cellular plant tissues.

The Double Quick Liver Tablets were alleged to be misbranded in that the statement "Active Ingredients: Buckthorn, Aloes, Mandrake, Senna," borne on the box, was false and misleading since it represented that buckthorn, aloes, mandrake, and senna were the sole active ingredients of the article, whereas the article in three of the shipments contained a material proportion of ginger

as an active ingredient and in the fourth it contained a material proportion of calomel as an active ingredient. It was alleged to be misbranded further in that the statement "Double Quick Liver Tablets * * * quick and strong action upon the Liver," borne on the box label, was false and misleading since it represented that the article was efficacious as a liver tablet and would exert a quick and strong action upon the liver; whereas it would not be efficacious for such purposes.

Analyses of samples of each of the five shipments of the Compound Herb Tea showed the following facts: (1) The product consisted essentially of plant material including rosemary and unidentified green leaves; (2) it consisted essentially of plant material, containing sassafras bark and rosemary leaves; (3) it consisted essentially of plant material including sassafras bark, chicory, red clover flowers and stems, green leaves resembling *Eupatorium*, senna leaves, and unidentified fine debris; (4) product consisted essentially of plant material including rosemary leaves, unidentified starchy material, and small pieces of root-like material; and (5) product consisted essentially of small pieces of leaves, stems, and unidentified plant debris. The Compound Herb tea was alleged to be misbranded in that the statement "Whites, Gonorrhoea, and Leucorrhoea," borne on the label, was false and misleading since they represented that the article was efficacious in the treatment of whites, gonorrhoea, and leucorrhoea; whereas it was not efficacious for such purposes.

Analysis indicated that the Blessed Herb Tea consisted essentially of plant material including couch grass, calamus, mistletoe, and unidentified plant debris. It was alleged to be misbranded in that the statements "For Bright Disease" and "for Bloody and Scalding Urine and Stricture," borne on the label, were false and misleading since they represented that it was efficacious in the treatment of Bright's disease and for bloody and scalding urine and stricture; whereas it was not efficacious for such purposes.

Analysis of the Herb Wash indicated that it consisted essentially of ground and powdered oak bark. It was alleged to be misbranded in that the statements, "For Female Disorder * * * It may be used freely, also for Gonorrhoea, or any Disorder of the Water Passage * * * in bad case of falling of the Womb," borne on the label, were false and misleading since they represented that the article was efficacious in the treatment of female disorder, gonorrhoea, any disorder of the water passage, and bad case of falling of the womb; whereas it was not efficacious for such purposes.

Analysis of the St. Bernard Tea indicated that it consisted essentially of plant material including sassafras bark, uva ursi, mallow flowers, buchu leaves, and unidentified plant debris. It was alleged to be misbranded in that the statements, "Very soothing in inflammation and irritation of the Kidneys and Bladder, Gravel, Backache and certain rheumatic affections * * * Tonic * * * Antispasmodic," borne on the label, were false and misleading in that they represented that it was soothing in inflammation and irritation of the kidneys and bladder, gravel, backache, and certain rheumatic affections, and that it was a tonic and an antispasmodic; whereas it would not be efficacious for such purposes.

All of the remedies were alleged to be misbranded further in that certain statements contained in circulars entitled "The Herbal Healer," "Dr. Lyncha A. Johnson Herbalist," and "Dr. Lyncha A. Johnson Herbal Health Herald," one or more of which accompanied each of the articles, were false and misleading in that they represented that herbs would be effective in the cure, mitigation, treatment, or prevention of the various ailments, diseases, and pathological conditions listed in said circulars, which included diabetes, Bright's disease, paralysis, fibri tumor, tuberculosis, cancer, epileptic fits, syphilitic diseases, and numerous other serious ailments; whereas herbs would not be effective for such purposes.

On November 20, 1940, a plea of guilty having been entered, the court imposed a fine of $1,500, and the defendant was sentenced to 6 months' imprisonment in a jail or Federal prison camp.

370. Misbranding of Elga Bust Developer. U. S. v. Myrtle E. Edwards (Elga Laboratories). Plea of guilty. Defendant placed on probation for a period of 4 years. (F. D. C. No. 2115. Sample No. 5904–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated below.

On September 11, 1940, the United States attorney for the Northern District of California filed an information against Myrtle E. Edwards, trading as Elga

Laboratories at San Francisco, Calif., alleging shipment on or about January 29, 1940, from the State of California into the State of Ohio of a quantity of Elga Bust Developer that was misbranded.

Analysis showed that the article consisted essentially of invert sugar, small proportions of calcium phosphate, and extracts of plant drugs, and water, colored with a red dye.

It was alleged to be misbranded in that the statements, "Elga Bust Developer. A Specialized normalizing Food designed to supplement nature, feeding systemically the sensitive, delicate, starved cells of immature, sagging or depleted breasts," borne on the bottle label, were false and misleading since they represented that it would develop the bust, that it was a specialized normalizing food designed to supplement nature, that it would feed systemically the sensitive, delicate, starved cells of immature, sagging, or depleted breasts, and that it was strictly a food; whereas it would not be efficacious for such purposes and it was not strictly a food, but was a drug. The article was also alleged to be misbranded under the provisions of the law applicable to food, as reported in F. N. J. No. 2096.

On February 4, 1941, a plea of guilty having been entered, the court placed the defendant on probation for a period of 4 years.

371. Misbranding of Hannon's Rub External Treatment. U. S. v. Hannon Medicines, Inc., and Louis A. Hannon. Pleas of guilty. Fines, $100. (F. D. C. No. 2846. Sample No. 9563–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter. The cartons for both sizes were unnecessarily large. The 1-ounce bottle occupied approximately 32 percent and the 2-ounce bottle approximately 38 percent of the space in the carton.

On April 19, 1941, the United States attorney for the Southern District of Mississippi filed an information against Hannon Medicines, Inc., Brookhaven, Miss., and Louis A. Hannon, alleging shipment on or about April 29, 1940, from the State of Mississippi into the State of Louisiana of a quantity of Hannon's Rub External Treatment which was misbranded.

Analysis showed that the article consisted essentially of camphor, soap, chloroform, water, and alcohol.

The article was alleged to be misbranded in that certain statements in the labeling were false and misleading in that they represented that it was efficacious in the treatment of rheumatism, arthritis, neuritis, croup, coughs, laryngitis, chest colds, paroxysms due to asthma, menstrual colic, sciatica, bursitis, lumbago and backache; that it would relieve severe sprains, headache, neuralgia, or rheumatism; that it was efficacious in the treatment of stiff muscles and joints which accompany rheumatism, lumbago, and neuralgia; whereas it would not be efficacious for such purposes. It was alleged to be misbranded further in that its container, i. e., carton, was so made, formed, or filled as to be misleading.

On May 5, 1941, pleas of guilty having been entered, the court sentenced the corporation and the individual each to pay a fine of $50.

372. Misbranding of Dr. Hunt's Cervical Spine Relaxer. U. S. v. Dr. Albert Thurlow Hunt. Plea of nolo contendere. Fine, $50. (F. D. C. No. 2110. Sample No. 11019–E.)

The labeling of this device bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On October 14, 1940, the United States attorney for the Southern District of California filed an information against Dr. Albert Thurlow Hunt, Los Angeles, Calif., alleging shipment on or about January 3, 1940, from the State of California into the State of Texas of a device known as Dr. Hunt's Cervical Spine Relaxer which was misbranded.

Examination showed that the device consisted of a sling fitting under the chin and around the back of the neck and riveted to a horizontal bar. A block and tackle were used to operate the device. One end of this block and tackle was inserted in the horizontal bar and the bar was to be fastened to a hook over a door or to some overhead point. The block and tackle were manipulated to cause a stretching of the operator's neck.

The device was alleged to be misbranded in that certain statements and designs appearing in the circular were false and misleading in that they represented that it was an effective and competent treatment to prevent the following disorders, or to overcome them if they already existed: Functional disorders of the head, throat and neck, headaches, insomnia, hay fever, nasal

catarrh, catarrhal deafness, enlarged tonsils, sinus troubles, pyorrhea, eye troubles, goiter, apoplexy, neck, shoulder and arm neuralgia, brachial neuralgia, draining sinuses, head noises, dizziness, tonsillitis, sinus congestion, bronchitis, bronchial asthma, eyestrain and crossed eyes, mastoid abscess, angina pectoris, mental aberration, curvature of the spine, exophthalmic goiter, laryngitis, various heart troubles, and many other distressing conditions which are benefited by improved circulation; that it constituted an effective and competent self-administered home treatment of many serious and painful disorders; that it would bring about the restoration of normal circulation; that it would give complete relief with no other treatment; that it was the best possible self-administered treatment for the relief of that great intractable group of head and throat disorders so disappointingly treated by other measures, that is, that it was an effective and competent treatment for said disorders; and that it would relax the cervical spine; whereas it was not an effective or competent treatment for such purposes.

On October 14, 1940, the defendant having entered a plea of nolo contendere, the court imposed a fine of $50.

373. Misbranding of Rogers' Mineral Extract. U. S. v. Lafayette Rogers (The Rogers Mineral Co.). Plea of nolo contendere. Fine, $25. (F. D. C. No. 2111. Sample No. 61879–D.)

The label of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On September 25, 1940, the United States attorney for the Southern District of Alabama filed an information against Lafayette Rogers, trading as the Rogers Mineral Co., Cullomburg, Ala., alleging shipment on or about January 25, 1940, from the State of Alabama into the State of Mississippi of a quantity of Rogers' Mineral Extract which was misbranded. The article was labeled in part: "Rogers' Mineral Extract Formerly Known as Acid Iron Earth."

Analysis showed that the article was a water solution containing approximately 6 percent of mineral matter, mainly, iron, aluminum, and sodium sulfates.

The article was alleged to be misbranded in that certain statements in the labeling were false and misleading in that they represented that it was efficacious in the internal and external treatment of indigestion, liver, kidneys and blood, hemorrhage of lungs, early stages of consumption, lung trouble, diarrhea or any bowel trouble, pellagra, rheumatism, cuts, burns, sores of all kinds, bruises, scalds, inactive liver, ulcerated stomach, liver and kidney trouble, flux and dysentery and other spring and summer diseases, run-down condition, ulcers, early stages of eczema, backache and general weakness, "T. B. of the bone," and skin diseases; that it was efficacious to prevent malaria, to regulate the appetite and to "cause the food to assimilate, which means strength, health and happiness"; that it was efficacious as a blood purifier; would remove pimples from the face; that it was a natural remedy and purifier which would cooperate with the blood system and action of the body, and thus give nature an opportunity to restore to the body that which it had lost; that it would cause the body to regain strength and its proper functioning power; that it possessed healing power; that it would insure health; that it was efficacious as a system builder; that it was efficacious to prevent cholera in hogs and chickens, and that it was efficacious in the treatment of sorehead in chickens; whereas it was not efficacious for such purposes.

On November 8, 1940, the defendant entered a plea of nolo contendere and the court imposed a fine of $25.

374. Misbranding of Sun Dried Nova Scotia Dulse. U. S. v. Gus E. Sjoberg (Coffin Fish Co.). Plea of nolo contendere. Fine of $150 on count 1. Imposition of sentence suspended on count 2 and defendant placed on probation for 9 months. (F. D. C. No. 2094. Sample Nos. 73116–D, 83523–D.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated below.

On August 22, 1940, the United States attorney for the Western District of Washington filed an information against Gus E. Sjoberg, trading as the Coffin Fish Co. at Seattle, Wash., alleging shipment on or about August 23 and December 27, 1939, from the State of Washington into the States of California and Oregon of quantities of dulse that was misbranded. It was labeled in part: "Sun Dried Nova Scotia Dulse * * * Imported and Packed by Coffin Fish Co. Seattle, U. S. A."

Examination showed that the article was a dark brown vegetable material, apparently dried seaweed.

The article was alleged to be misbranded in that representations on the cartons and in the circulars that it would be efficacious in the treatment of goiter and constipation; would be efficacious for preventing scurvy; would be efficacious in the prevention of all diseases of the thyroid; would maintain resistance of the body to infection; would be efficacious as a stimulant and benefit to the stomach; would have a wonderfully soothing effect in cases of intestinal flu, colds in the throat or lungs; and that physicians would advise the use of the article in all troubles resulting from an insufficient daily supply of iodine, were false and misleading since it would not be efficacious for the said purposes and since physicians would not advise its use in all troubles resulting from an insufficient daily supply of iodine.

On December 20, 1940, a plea of nolo contendere having been entered by the defendant, the court imposed a fine of $150 on count 1. Imposition of sentence was suspended on count 2 and the defendant was placed on probation for 9 months.

375. Misbranding of World Famous New Life Laxative Tonic. U. S. v. Harry B. Kahng (New Life Laboratories and Oriental New Life Medicine Co.). Tried to a jury. Verdict of guilty. Defendant placed on probation for 1 year. (F. D. C. No. 952. Sample Nos. 5425–D, 82986–D.)

The labeling of this product bore false and misleading representations regarding its composition and its efficacy in the conditions indicated below, and falsely represented that the article contained no harmful or habit-forming drugs.

On June 18, 1940, the United States attorney for the Northern District of Georgia filed an information against Harry B. Kahng, trading as the New Life Laboratories and as the Oriental New Life Medicine Co. at Atlanta, Ga., alleging shipment on or about October 2 and December 7, 1939, from the State of Georgia into the States of Alabama and Florida of quantities of the above-named drug product which was misbranded.

Analyses showed the article contained Epsom salt, free sulfur, senna, anise, cascara, licorice, and unidentified substances.

The article was alleged to be misbranded in that the statements, "New Life * * * System Cleanser and Tonic for Every Member of the Family * * * A Real Remedy for every one," borne on the cartons, were false and misleading in that they represented that it would be efficacious in producing the improvement in health, well-being, and vigor implied in the expression "New Life"; that it would be efficacious as a system cleanser and tonic for every member of the family and was a real remedy for everyone; whereas it would not be efficacious for such purposes.

It was alleged to be misbranded further in that the statements, "Highly recommended for constipation, the usual cause of stomach disorder, kidney, bladder trouble, gas pains, biliousness, thus promoting better health in general and bring resistance to many common diseases," borne on the cartons, were false and misleading in that they represented that constipation is the usual cause of stomach disorders, kidney and bladder troubles, gas pains, and biliousness, and that the article would be efficacious in the prevention of the usual stomach disorders, kidney and bladder troubles, gas pains and biliousness, and would promote better health in general and bring resistance to many common diseases; whereas constipation is not the usual cause of stomach disorders, kidney and bladder troubles, gas pains and biliousness, but said disorders and ailments have many and varied causes, and the article would not be efficacious in prevention of the conditions named in the said statements, would not promote better health in general, and would not bring resistance to many common diseases.

It was alleged to be misbranded further in that the statements, "New Life A preparation of many centuries old world famous Oriental Gen Sen formula. * * * Directions: Take regularly at bed time ½ teaspoonful in ½ glass warm or cold water (stirred well). Regulate dose to bring 2 evacuations of bowels daily by either increase or decrease doses, as some individuals are different than others. Children proportion to the age. If desired, add sugar to improve taste. * * * Known to be highest value of herbal tonic. Contains no harmful or habit forming drugs," borne on the cartons, were false and misleading in that they represented that the article was a preparation of "many centuries old world famous Oriental Gen Sen formula," that it was an herbal tonic and contained no harmful or habit-forming drugs; whereas it was not a preparation of "many centuries old world famous Oriental Gen Sen formula," it was not an herbal tonic since it contained Epsom salts and free sulfur, mineral substances, and contained drugs which when used in the dosage and with the frequency prescribed in the labeling might be harmful and habit-forming.

On October 24, 1940, the defendant having entered a plea of not guilty, the case came on for trial before a jury. The trial was concluded on October 28 on which date the court, after hearing arguments of counsel on behalf of the Government and the defendant, instructed the jury as follows:

UNDERWOOD, *District Judge.* "Gentlemen of the jury, this is an indictment which is not evidence, but merely the charges of the Government brought by the United States against this defendant charging him with the violation of a certain Federal law to which I will direct your attention later.

"To this indictment, the defendant has entered a plea of not guilty and this plea puts the burden upon the Government to prove him guilty of the offense charged beyond a reasonable doubt. Before instructing you with respect to the law governing the particular offense charged in the indictment, there are some general rules of law to which I will call your attention.

"It is the judge's duty to instruct you as to the law of the case, and you must accept the law as given by the court, but you are the sole judges of the facts in the case, the weight of the evidence, and credibility of the witnesses. If the court should express, or you think he has expressed any opinion whatever, with respect to the facts in the case, you are not bound by it, but should follow your own conclusions and make your own finding of fact since I have stated you are the sole judges of the facts. You should take the law as charged by the court and apply it to the evidence and render such verdict that you find the law and the evidence demands.

"The defendant comes into court with the presumption of innocence in his favor, and that presumption remains with him throughout the trial, until he has been shown to be guilty beyond a reasonable doubt of the offense charged in the indictment. This presumption has relation to every fact that must be established in order to prove his guilt beyond a reasonable doubt.

"Reasonable doubt does not mean just any possible doubt that you might have, but it means such reasonable doubt as a careful, prudent, and reasonable man ought to entertain in the circumstances proven. That is, it means reasonable moral certainty that all reasonable doubt of defendant's guilt is excluded by the evidence.

"Now in weighing the evidence in this case, you should consider the circumstantial, as well as the direct testimony, for frequently it is not possible to prove facts by direct testimony. The weight of the evidence and the credibility of the witnesses, as I have stated, what are the force and effect of the facts and circumstances proved in this case are questions solely for your determination.

"In weighing the testimony and the credibility of the witness the jury may, among other things, consider his manner and demeanor on the stand, his feeling, interest, prejudice or bias, if any; his means of knowing what he is testifying to; the probability or improbability of what he testifies to; the consistency or inconsistency of his statements with other facts proved in the case; the reasonableness or unreasonableness of his testimony and also his personal credibility, so far as it may legitimately appear from the trial of the case. The number of witnesses on any contested point may be considered by you, but the truth is not always with the greater number.

"If conflicts in the testimony of witnesses exist, it is your duty to reconcile them without imputing perjury to anyone, if you reasonably can, but if you can't do this reasonably, of course, you will believe the one that you think most worthy of belief.

"Certain expert testimony has been introduced in evidence. You will consider that and treat it in the same manner that you do any other testimony in the case. The simple fact that it was offered by experts does not compel you to take their testimony in preference to any other, but you should give the testimony of expert witnesses the same weight, the same consideration, everything else being equal, as that of other witnesses. That is, give such opinions, and receive of them such weight as you deem them entitled to. Where opinions are given by experts based upon hypothetical questions, you should carefully examine the statement of facts that have been assumed in the question and determine whether or not such facts have been proven, and what the opinion is in the light of what has actually been proven.

"This indictment is in two counts. The first, charging the defendant with violating the Federal Food, Drug, and Cosmetic Act, by introducing into interstate commerce a certain drug known as New Life. It is alleged that the interstate shipment charged in the indictment was made on June 25, 1938, from Atlanta, Ga., to C. W. Barnard, in Birmingham, Ala.

"The second count charges a similar offense on the same day, in the same language except that the interstate shipment was from Atlanta, Ga., to Hugh E. Tuck, Tallahassee, Fla.

"In both counts of the indictment it is charged the misbranding consisted of certain representations on the labels of the drug which the Government maintains were false and misleading.

"First, it is claimed that the following expressions were false and misleading. To wit: 'New Life * * * System Cleanser and Tonic for every member of the family * * * a real remedy for every one.'

"Second, the Government maintains that the article was further misbranded in that the labels stated the drug was 'highly recommended for constipation, the usual cause of stomach disorder, kidney, bladder trouble, gas pains, biliousness, thus promoting better health in general and bringing resistance to many common diseases.'

"The Government's contention is, while the label literally recommends the drug only for constipation, nevertheless, the immediate association of the category of diseases which the label asserts are usually caused by constipation, was misleading and really amounted to an assertion that the drug was a remedy for such diseases, as well as for constipation.

"The Government further maintains that the statement on the label that the drug was 'a preparation of many centuries old, world famous Oriental Gen Sen formula,' was false and misleading; and that if the preparation was taken as directed on the label, it would be harmful and habit-forming; and further, that the claim that the drug was 'known to be of highest value of herbal tonic, Contains no harmful or habit-forming drug' was false and misleading.

"The defendant, on the other hand, denies all these charges and contends the drug in question was not represented on the label to be anything more than a satisfactory remedy for constipation and that the defense in the case shows that all of its ingredients taken separately, or in the combination indicated, were suitable and helpful in the treatment of constipation and have been used for a great many years by reputable physicians and recognized in the standard pharmacopoeia as suitable for the treatment of constipation, and that there was not a single ingredient that was either harmful or habit-forming; that the preparation is a recognized and satisfactory remedy for constipation and especially valuable for people seeking relief from such trouble who are unable or unwilling to consult physicians and to secure specific treatment and prescriptions from them.

"Defendant further contends there is no evidence to show that this preparation is not an old world famous Gen Sen formula, and, as a matter of fact it is such. I do not recall any evidence produced by the Government that the preparation is not an Oriental formula, but the evidence of the Government was merely that the doctors testifying did not know of any such Oriental formula.

"Of course the burden of proof is on the Government to prove beyond a reasonable doubt the charges in the indictment.

"Defendant further contends that the label does not represent the preparation to be a remedy for stomach disorder, kidney, bladder trouble and so forth, and that the words used would not mislead the general public or anyone purchasing the drug into believing that it was represented to be a remedy for such diseases, but that such purchaser would clearly understand the remedy was recommended for constipation only.

"These contentions raise questions of fact which the Government must prove beyond a reasonable doubt, and as I have said before, you are the sole judges of the facts.

"Now the law provides that a drug or device shall be deemed to be misbranded if its label is false or misleading in any particular, and it is for you to determine from the evidence in this case and instructions given you by the court, whether or not the label on the drug as quoted in the indictment is false or misleading in the sense the term as used in the label, in the terms of misbranding as used in the act, the act itself provides if the article is alleged to be misbranded, it is because the label is misleading. Then in determining whether the label is misleading there should be taken into account, among other things. not only representations made, or suggested by statement, word, design, description, or any combinations thereof, but also the extent to which the label fails to reveal, if there is any such failure, facts material in the light of such representation, or material with respect to consequences which may result from the use of the article to which the label relates, under

the conditions of use prescribed in the label thereof, or under such conditions of use as are customary or usual.

"In determining whether or not the label in question in this case was false and misleading, you must approach the question from the viewpoint of a man of ordinary intelligence who might be suffering from constipation and desirous of being relieved of it. That is, the language used on the label should be given the meaning ordinarily conveyed by it, to whom it is addressed, and if you find beyond a reasonable doubt that the language so construed is false and misleading, then you would have to find the defendant guilty.

"The act seeks to protect those who might be induced to purchase the article by the representation made in the label, and the proper test for the construction of such language is what it means to such persons, and not necessarily to those who are skilled in medicine and medical or pharmaceutical science, capable of making necessary distinctions. Its purposes are to secure purity in foods and drugs; to inform purchasers of what they are buying; to prevent injury to the public health, and to require the manufacturer to be honest in his statements, those resulting from insufficient directions and ambiguity, as well as statements that are false, come within the contemplation of the act.

"Now gentlemen of the jury, if from the evidence in this case and under the instructions that the court has given you, you find this defendant guilty beyond a reasonable doubt of the offense charged in the indictment, then the form of your verdict would be, 'We, the jury, find the defendant guilty.' On the other hand, if you find him not guilty, then the form of your verdict would be, 'We, the jury, find the defendant not guilty.' You may retire."

The jury, after due deliberation, returned a verdict of guilty and the court placed the defendant on probation for 1 year.

SEIZURES

376. Misbranding of Electreat Mechanical Heart. U. S. v. 6 Electreat Mechanical Hearts. Tried to the court. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 1736. Sample No. 16222–E.)

The labeling accompanying this device bore false and misleading representations regarding its efficacy in the conditions indicated below.

On April 2, 1940, the United States attorney for the Western District of Missouri filed a libel against six of the above-named devices at Kansas City, Mo., alleging that the article had been shipped in interstate commerce on or about March 6, 1940, by the Electreat Manufacturing Co. from Peoria, Ill.; and charging that it was misbranded.

Examination showed that the device consisted of dry cells, a small buzzer coil, and various attachments intended to apply electrical currents to the body.

The article was alleged to be misbranded in that statements appearing on the carton and in an accompanying circular and booklet were false and misleading since they represented that it was efficacious for the purposes recommended; whereas it was not efficacious for such purposes. The respect in which the labeling was false and misleading appears in the opinion of the court.

On May 5, 1940, the Electreat Manufacturing Co. appeared as claimant and on July 18, 1940, filed an answer denying the allegations of misbranding. On February 28, 1941, the case having come on for trial before the court and the evidence having been heard and considered, the court handed down the following opinion sustaining the Government's allegations:

COLLETT, *District Judge.* "On March 6, 1940, six devices called Electreat Mechanical Hearts were mailed in interstate commerce[1] from Peoria, Ill., to Kansas, City, Mo., for the purpose of sale at the latter place. The devices were seized by the Government and libel proceedings instituted at Kansas City, Mo., for the purpose of bringing about the destruction of the devices.

"The Federal Food, Drug, and Cosmetic Act of June 25, 1938 (Title 21, Sec. 301 et seq. U. S. C. A.) authorizes the destruction of misbranded devices.[2] The

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[1] "Sec. 321 (b): The term 'interstate commerce' means (1) commerce between any State or Territory and any place outside thereof * * *."

[2] "Sec. 334 (a): Any * * * device * * * that is * * * misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found * * *."

term 'device' is defined in the act.[3] The statute provides that if the device is alleged to be misbranded because of misleading labeling, in the determination of that question there shall be taken into account, among other things, not only representations made in the labeling but also the extent to which the labeling fails to reveal material facts.[4] 'Labeling' is defined to include all labels and other written, printed, or graphic matter upon the article or any of its containers or wrappers or accompanying the article.[5] The libel charges false and misleading labeling. The good faith of the manufacturer is not an issue. The inherent dangerousness of the device or lack of it is of no consequence. The issue is simply whether the claims made for the device are false or misleading.

"The principal and most numerous claims made for the device are contained in a booklet which accompanied the devices seized. There the device is referred to as 'The Mechanical Heart.' In the language of the booklet it will relieve pain, strengthen weak eyes, soothe sore eyes, improve the hearing, cure earache, moisten dry noses or dry running noses, thicken thin lips, relieve toothache, strengthen the voice, relieve sore throat, build up weak lungs, relieve pleurisy, strengthen the kidneys, cure lumbago, relieve constipation, soothe the piles, is good for neuritis, subtracts pain from burns, relaxes the muscles in a stiff thumb and soothes the pain in a mashed finger, retards or accelerates the development of a boil, heals broken noses, relaxes muscle cramps, is good for varicose veins and will warm cold feet or stop the foot from perspiring.

"The booklet undertakes to demonstrate 'why the good die young,' what the 'father and mother' of disease is, the cause of wakefulness, how to grow strong, and the corrective qualities of the device in each instance.

"It then gives specific directions about how to use the Electreat for the treatment of headache, neuralgia, sinus congestion, neuritis, sore throat, weak lungs, athletic strains, lumbago, rheumatism, gout and tired feet, stomach, indigestion and cramps, kidney and bladder trouble, liver disorders, constipation, piles, sexual weakness male and female, menstruation, menopause, enlarged prostate, paralysis, deafness and catarrh, toothache, eye ailments, asthma, hay fever, flu, broken bones, burns, cuts, sores, hardening of arteries, cramps of the calf, nervousness, to reduce weight or increase weight as desired, beautification of the skin, enlarge the bust and increase the flow of milk, and to stop falling hair. Then follows a number of testimonials affirming the efficacy of Electreat for the treatment of many and sundry bodily ailments ranging from congenital and jake-leg paralysis through heart ailments, piles, rejuvenation, to appendicitis and female trouble. The testimony of the manufacturer who intervened in the cause as claimant, indicates that the theory upon which the multitudinous claims were made was that the instrument produces a faradic electrical current with the alternating impulses occurring at the rate of from 140 to 180 times a second, which would cause the muscles and muscular tissue of the human body to contract and relax with beneficial results. The instrument is simple enough. It consists of a cylindrical metal container having much the appearance of an ordinary flashlight, approximately 10 to 11 inches long, an inch and a half in diameter with two small flashlight batteries in one end and in the other two coils. The primary coil is wound upon a soft iron core. The secondary coil is so wound that it may be moved longitudinally over the primary coil by means of a button attached to it and extending through the metal cylinder much as the switch on an ordinary flashlight is arranged. A common vibrator such as might be used on the old-fashioned doorbell, makes and breaks the current from the battery and transforms the galvanic current from the battery into the faradic or alternating current, which is delivered to the body through a projection on one end of the instrument. The strength of the charge delivered to the body from the instrument is increased or decreased by means of sliding the secondary coil further over or away from the primary coil.

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[3] "Sec. 321 (h): The term 'device' * * * means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals."

[4] "Sec. 321 (n): If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual."

[5] "Sec. 321 (m): The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

"An adequate amount of highly respectable and convincing testimony was offered by the Government to demonstrate that even the principle sought to be followed by the makers of the instrument could not be applied with this instrument. It was explained that the speed or rapidity at which muscular tissue could contract and relax was much less than the rate at which the vibrations occurred in this instrument and the alternating impulses were given, and hence the only effect from the use of the instrument on the muscles of the body was to cause them to contract and remain so until the instrument was removed, the batteries wore out, or the muscles relaxed from fatigue. Many of the particular claims made for the instrument were specifically referred to by the witnesses. In each instance the explanation of why the instrument could not produce the results claimed for it was most convincing.

"Among others appearing for the Government was the eminent physiologist, Dr. Carlson. His testimony and the illustrations he gave supporting his conclusions were in all respects as fully convincing of the accuracy of his judgment as was his test for the determination of which of two fluids was a sugar solution.[6]

"The extent of the accuracy of the actual claims made for the Electreat in the literature accompanying it may be summarized much as one of the witnesses expressed it when, in describing a diagram of the human anatomy with accompanying descriptive matter which appeared in one of the exhibits, he stated that there was an element of truth in the diagram, the element of truth being—that the head was on the right end in the picture and the 'rump' appeared in the proper position. From a practical standpoint, the benefit to be derived from the use of the instrument was tersely stated by one of the several leading physicians of Kansas City, to be that the use of the instrument would not injure one if there was nothing the matter with him, but that if a person was suffering from any disorder or ailment its use might and probably would be injurious.

"Further detailed reference to the facts should be unnecessary to demonstrate the irresistible conclusion arising from the evidence that the claims made for the devices in the literature accompanying them were as falsely misleading as might well be possible by the use of the English language. The conclusion follows that the act of Congress has been violated and the requested order for the destruction of the devices must be made.

"It is beyond the issues in this proceeding to consider the question of whether, if the devices were properly described and labeled and their efficacy stated without exaggeration, the devices could be barred from the mails and interstate commerce. Hence, evidence bearing upon that question admitted subject to objection, is excluded from consideration.

"Neither is the question of whether the manufacturer acted in good faith in an honest belief that the devices would do the things claimed for them an issue in this proceeding. The Government does not seek a penalty in this case other than the destruction of the devices. Evidence bearing upon that question, likewise admitted subject to objection, should also be excluded.

"Formal findings of fact and conclusions of law are filed herewith. Judgment will be entered in accordance with the views herein expressed."

On February 28, 1941, judgment was entered (amended March 10, 1941) ordering that the marshal destroy the product. On March 20, 1941, the claimant filed a motion for a rehearing and application for stay of proceedings which were argued April 25, 1941, and denied by the court without opinion.

377. Misbranding of El Aguinaldo Cuban Honey. U. S. v. 50 Bottles of El Aguinaldo Cuban Honey (and 3 other seizure actions involving the same product). Default decrees of condemnation. Portion of product ordered destroyed; remainder ordered delivered to charitable institutions. (F. D. C. Nos. 2498, 2725, 3438, 3462. Sample Nos. 8932–E, 8937–E, 27491–E, 27495–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On August 6, September 4, November 27, and December 5, 1940, the United States attorneys for the District of Minnesota and the Southern District of Ohio filed libels against 50 bottles of El Aguinaldo Cuban Honey at St. Paul, Minn.; 118 bottles of the same product at Minneapolis, Minn.; and 171 bottles at Cincinnati, Ohio, alleging that the article had been shipped in interstate commerce within the period from on or about December 27, 1939, to on or about

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[6] "Time magazine, February 10, 1941, page 44, l. c. 47: Another time he had two beakers of liquid before him: one containing urine, the other, sugar solution. He stuck his finger in one of the containers, tested it and said: 'Ya, dot's sugar.'"

October 29, 1940, by Cuban Honey, Inc., from Lansing, Mich.; and charging that it was misbranded.

Examination of the article showed that it was honey.

It was alleged to be misbranded in that the labeling which accompanied it bore representations that carbohydrates in this form (honey) mean "pep" and pep means "a better you"; that it contained many of the necessary mineral salts; that it had been clinically tested, and that such tests had been carried on in cases of bronchial asthma and bronchitis under the care of reputable physicians; that it had been found to be a desirable food supplement to a bland diet in cases of stomach ulcers and other digestive disorders; that the contents of the stomach had been examined at specific intervals and X-rays taken and that all cases showed much greater improvement when El Aguinaldo Cuban Honey was a part of the diet than without it; that the diets used tended to relieve discomfort, increase vitality, improve the appetite and provide a mild laxative; that it had been used in various types of illness with very pleasing results in many cases; that the article would be efficacious as a palliative for local irritations of nose and throat associated with coughs, colds, asthma, and bronchitis; that for sinus and hay fever it should be diluted with water and used as a nasal spray and should be taken internally 1 or 2 teaspoonfuls one-half hour before meals and before retiring; that in stomach ulcers where a soft bland diet would be prescribed and in other digestive disorders it should be used as a special-purpose food, which representations in the labeling were false and misleading since it was not efficacious for the purposes represented and suggested by the labeling.

On September 19 and October 25, 1940, and January 25, 1941, no claimant having appeared, judgments of condemnation were entered and the lot seized at St. Paul was ordered destroyed and those seized at Minneapolis and Cincinnati were ordered delivered to charitable institutions.

378. Misbranding of Brown's Bron-Ki. U. S. v. 27 1-gallon Cans and 8 5-gallon Cans of Bron-Ki. Default decree of condemnation and destruction. (F. D. C. No. 2364. Sample Nos. 14254–E, 14255–E.)

The labeling of this veterinary product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On July 16, 1940, the United States attorney for the District of Delaware filed a libel against 27 gallon cans and 8 5-gallon cans of Brown's Bron-Ki at Dagsboro, Del., alleging that the article had been shipped in interstate commerce within the period from on or about May 10 to May 17, 1940, by Brown's Bron-Ki Co. from Lancaster, Pa.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of kerosene with small quantities of volatile oils such as oil of spruce, oil of eucalyptus, oil of tar, and oil of citronella. Bacteriological examination showed that it was devoid of antiseptic properties.

The article was alleged to be misbranded in that its labeling contained representations that it was efficacious in the treatment of colds, bronchitis and other diseases of the respiratory tract in poultry, that it was efficacious as a preventive and treatment for brooder pneumonia, that it contained healing and antiseptic ingredients, and that if treatment was undertaken immediately, infection would not develop; whereas the article would not be efficacious for such purposes.

On August 27, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

379. Misbranding of Colicramp Drops. U. S. v. 114 Packages of Colicramp Drops. Default decree of condemnation and destruction. (F. D. C. No. 3577. Sample No. 46126–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter. It was packed in a very narrow, paneled bottle in a carton considerably larger than was necessary.

On December 27, 1940, the United States attorney for the Southern District of New York filed a libel against 114 packages of Colicramp Drops at New York, N. Y., alleging that the article had been shipped in interstate commerce on or about September 6, 1940, by A. G. Groblewski & Co. from Plymouth, Pa.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of alcohol, ether, and small amounts of peppermint, ammonia, ginger, and extracts of plant drugs.

It was alleged to be misbranded in that the following statements in the labeling were false and misleading: "Colicramp * * * For relief of Gas in Stomach, Wind Pains in Stomach * * * Heavy or Bloated Feeling after Eating. Also

for Colicky-Like Gas Pains Peculiar to Women (similar statements in foreign language)," since the article was not efficacious for such purposes. It was alleged to be misbranded further in that its container was so made, formed, or filled as to be misleading

On March 4, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

380. Misbranding of Colusa Natural Oil. U. S. v. 12 Bottles of Colusa Natural Oil. Default decree of condemnation and destruction. (F. D. C. No. 2264. Sample No. 16069–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On or about July 9, 1940, the United States attorney for the Western District of Missouri filed a libel against 12 2-ounce bottles of Colusa Natural Oil at Kansas City, Mo., alleging that the article had been shipped in interstate commerce on or about May 21, 1940, from Hollywood, Calif., by C. W. Colgrove; and charging that it was misbranded.

Analysis showed that the article consisted of crude petroleum oil.

It was alleged to be misbranded in that representations in the labeling that it was efficacious in the treatment of athlete's foot or ringworm; that it was efficacious to relieve painful and irritating itching and unsightly blemishes on hands; that it was efficacious in the treatment of eczema, psoriasis, acne, foot burns and cuts and poison oak; that it was efficacious on surface skin irritations acting as a stimulant increasing circulation and thereby aiding in the healing; that it possessed penetrating qualities and reducing properties which would help relieve the discomfort and pain; and that it possessed detergent and mild antiseptic action which would inhibit the spreading of skin irritations and help restore the normal skin surface, were false and misleading since it would not be efficacious for such purposes.

On August 3, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

381. Misbranding of Colusa Natural Oil. U. S. v. 257 1-ounce Bottles of Colusa Natural Oil. Default decree of destruction. (F. D. C. No. 2263. Sample No. 16068–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated below.

On or about July 9, 1940, the United States attorney for the Western District of Missouri filed a libel against 257 1-ounce bottles of the above-named product at Kansas City, Mo., alleging that the article had been shipped in interstate commerce on or about December 16, 1939, by the Swan Manufacturing Co. from San Francisco, Calif.; and charging that it was misbranded.

Examination showed that it was crude petroleum oil.

The article was alleged to be misbranded in that the following statements appearing on the label were false and misleading since they represented that it was efficacious for the purposes recommended, whereas it was not efficacious for the purposes recommended: "For external use in the relief and treatment of * * * cuts, eczema, psoriasis, acne, skin blemishes, pyorrhea, varicose veins * * * and hay fever."

On August 3, 1940, no claimant having appeared, judgment was entered ordering destruction of the product.

382. Misbranding of Durets. U. S. v. 40 Packages of Durets. Default decree of condemnation and destruction. (F. D. C. No. 2161. Sample No. 14678–E.)

The labeling of this product bore false and misleading representations regarding the conditions indicated hereinafter.

On June 5, 1940, the United States attorney for the Eastern District of Pennsylvania filed a libel against 40 packages of Durets at Reading, Pa., alleging that the article had been shipped in interstate commerce on or about May 25, 1940, by James Lawrence Co., Inc., from New York, N. Y.; and charging that it was misbranded.

Analysis showed that the article consisted of tablets, each containing theophylline (½ grain), methenamine (1 grain), sodium biphosphate (2.3 grains), and starch.

The article was alleged to be misbranded in that representations in the labeling that it would help to drive out poisonous body wastes; would relieve loss of sleep; was efficacious in the treatment of backache, headache, mental depression, excessive tiredness, pains in the groin, burning, frequent, smarting, painful, or

scanty urination; that it was efficacious in the treatment of rheumatic muscular pains or joint pains due to chronic prostatitis; that it was efficacious in the treatment of inflammation or catarrh of the bladder, inflammation of the pelvis of the kidney, kidney stone, or bladder stone, and urethritis; and that it would help purify the urinary passages, and help nature heal, were false and misleading since it was not efficacious for such purposes.

On June 27, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

383. Misbranding of grapefruit juice. U. S. v. 94 Cases of Grapefruit Juice. Consent decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 3516. Sample No. 4353–E.)

The label of this product bore false and misleading representations regarding its efficacy in the conditions indicated below.

On or about December 27, 1940, the United States attorney for the Northern District of Illinois filed a libel against 94 cases of grapefruit juice at Chicago, Ill., alleging that the article had been shipped in interstate commerce on or about July 4, 1940, by Tolson Davies Co. from Brownsville, Tex.; and charging that it was misbranded. The article was labeled in part: "Perk-Up * * * Unsweetened Grapefruit Juice."

The article was alleged to be misbranded in that the statements, "Recommended * * * as a help in the prevention of colds and * * * also helpful in keeping the system on the 'alkaline side,'" were false and misleading. It was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 1904.

On February 3, 1941, the Tolson Davies Co., claimant, having admitted the allegations of the libel and having consented to the entry of a decree, judgment of condemnation was entered and it was ordered that the product be released under bond conditioned that it be properly relabeled.

384. Misbranding of Kru-Lax. U. S. v. 270 Packages of Kru-Lax. Default decree of condemnation and destruction. (F. D. C. No. 2293. Sample No. 9759–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated below.

On June 28, 1940, the United States attorney for the Northern District of Alabama filed a libel against 270 packages of Kru-Lax at Birmingham, Ala., alleging that the article had been shipped in interstate commerce on or about May 22, 1940, by the Oriental Laboratory from St. Louis, Mo.; and charging that it was misbranded.

Analysis showed that it consisted of Epsom salt, sulfur, and ground plant material including licorice, anise, buchu, and laxative plant drugs.

The article was alleged to be misbranded in that the following statements appearing in the circular distributed with it were false and misleading since it was not efficacious for the purposes recommended: "Oriental Herbal Compound * * * to relieve constipation * * * The usual cause of the following ailments: Stomach: Indigestion, Dyspepsia, Bloating, Headache, Heartburn, Palpitation, Gas Pains. Liver: Biliousness, Dizzy Spells, Sluggishness. Kidney: Rheumatism, Pain in Neck, Shoulders, Arms, Arthritis, Lumbago, Sciatica, Gout, Prostate Trouble. Female Complaints. Bladder: Inflammation and Getting Up at Night. Skin: Pimples, Blackheads, Boils, Rash, Itching. Blood: Thin, Weak, High or Low Blood Pressure. Bowels: Piles, Tape Worm, Appendicitis, Colic, Overweight, Underweight. * * * A person with proper working bowels will never have appendicitis. If the liver is working properly will never catch cold. With properly working bowels and liver the germs of tuberculosis, cold, catarrh, typhoid or any other forms of contagious or acute disease cannot gain foothold in the system. It has been tested and proved to be a fact. We claim Kru-Lax will regulate the bowels and liver. If you just realize what constipation means to your health, or the health of some loved one, if you just knew from the medical viewpoint the human wreckage that is charged to constipation, you would not lose a moment in trying a package of this wonderful remedy. It is so little in price but so great aid to general health. Try it and be convinced."

On July 31, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

385. Misbranding of Natural Mineral Extracts. U. S. v. 38 Bottles of Natural Mineral Extracts. Default decree of condemnation and destruction. (F. D. C. No 1888. Sample No. 4661–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On May 6, 1940, the United States attorney for the Northern District of Indiana filed a libel against 38 bottles of Natural Mineral Extracts at Whiting, Ind., alleging that the article had been shipped in interstate commerce on or about February 13, 1940, by Colonial Drug Co. from Tulsa, Okla.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of ferric sulfate and water with small proportions of aluminum, calcium, and magnesium compounds.

The article was alleged to be misbranded in that representations in the labeling that it was efficacious to maintain the mineral balance, keep the system in perfect health, give new life to weakened and general run-down conditions of the system and resistance against attacks of germs and infection, that it was efficacious as a tonic for run-down, anemic conditions; that it was efficacious in the treatment of indigestion, stomach, liver, and intestinal disorders, ulceration of the stomach, kidney and bladder disorders, female trouble, high blood pressure, rheumatism, and many other run-down conditions of the blood; that it was efficacious in the external treatment of eczema and other skin conditions, was efficacious in the treatment of sore throat, tonsilitis, bleeding gums, enlarged prostate glands of old and middle-aged men; internal hemorrhoids, bleeding piles, old sores, pimples, carbuncles, toothache. itch: that it would stop the flow of blood instantly; and that it was efficacious when administered internally as a blood purifier, that it would bring comfort and health and was efficacious for general debility and many other chronic ailments, were false and misleading since it would not be efficacious for the purposes recommended.

On June 22, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

386. Misbranding of Natural Ray Mineral Water. U. S. v. 280 Cases and 13 Bottles of Natural Ray Mineral Water. Default decree of condemnation. Water dumped and bottles sold. (F. D. C. No. 1099. Sample Nos. 75476–D, 75477–D.)

The labeling of this product bore false and misleading representations regarding its efficacy for the conditions indicated below.

On November 29, 1939, the United States attorney for the Eastern District of Ohio filed a libel (and on December 20, 1939, an amended libel) against 280 cases each containing 6 half-gallon bottles and 135 gallon bottles of the above-named product at Cleveland, Ohio, alleging that the article had been shipped in interstate commerce on or about August 11, 1939, by the Natural Ray Mineral Water Co. from St. Louis, Mich.; and charging that it was misbranded.

Examination showed that the article was a moderately mineralized water, slightly alkaline, the mineral constituents consisting for the most part of calcium bicarbonate, calcium sulfate, and magnesium sulfate with small proportions of other inorganic constituents.

The article was alleged to be misbranded in that the following statements appearing in the labeling were false and misleading, since it was not efficacious for the purposes recommended: (Label attached to the ½-gallon and 5-gallon bottles) "Natural Ray Mineral Water From the Spring of Michigan Magnetic Mineral Water Co."; (label attached to 5-gallon bottles only) "* * * it has proven remarkably successful in the treatment of rheumatism, uric acid and kidney disorders"; and (bags enclosed in the case with ½-gallon bottles) "Natural Ray Mineral Water Will Help you Maintain as Well as Regain Your Health * * * Successfully used for seventy years in the treatment of constipation–uric acid–stomach–kidney troubles–and rheumatic conditions. * * * When used primarily as a Health Water, serve at room temperature."

On September 23, 1940, no claimant having appeared, judgment of condemnation was entered and it was ordered that the water be dumped and the bottles sold.

387. Misbranding of Naturzelp. U. S. v. 34 Bottles of Naturzelp. Consent decree of condemnation and destruction. (F. D. C. No. 1862. Sample No. 3207–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On April 25, 1940, the United States attorney for the Western District of New York filed a libel against 34 bottles of Naturzelp at Arcade, N. Y., alleging that the article had been shipped in interstate commerce on or about January 1, 1940, by the Neutro Distributing Association from Columbiana, Ohio; and charging that it was misbranded.

Analysis showed that the article consisted essentially of Epsom salt, sodium salicylate, and extracts of plant drugs including licorice and a laxative plant drug.

The article was alleged to be misbranded in that its labeling contained representations that it was efficacious as a general purifier; that it would act directly upon the liver and purge it of its excess toxins; would help the flow of bile; would be efficacious in the relief of rheumatism, arthritis, neuritis, lumbago; that it would act as a tonic for the stomach, liver, kidneys, and bowels; would make the digestive organs clean; improve the system in general; overcome constipation, remove poisons, restore normal alkaline dominance, render the system less susceptible to disease, relieve liver congestion; would get rid of the symptoms of diabetes, i. e., loss of weight, thirst, hunger, frequency of urination, and would drive the sugar from the urine; and that it would have a diuretic action upon sluggish kidneys, which representations were false and misleading since it was not efficacious for the purposes recommended

On November 25, 1940, the claimant, the Neutro Distributing Association, having withdrawn its claim and having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

388. Misbranding of Parkelp and Parkelp Tablets. U. S. v. 10 Cartons of Parkelp and 58 Cartons of Parkelp Tablets. Default decree of condemnation and destruction. (F. D. C. No. 3265. Sample Nos. 44487–E, 44488–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On October 29, 1940, the United States attorney for the District of Colorado filed a libel against 10 cartons each containing 7 ounces of Parkelp, 17 cartons each containing 200 Parkelp Tablets; 31 cartons each containing 500 Parkelp Tablets, and 10 cartons each containing 800 Parkelp Tablets at Denver, Colo., which had been consigned by Philip R. Park, Inc., alleging that the article had been shipped in interstate commerce on or about August 2, 1940, from San Pedro, Calif.; and charging that it was misbranded.

Analysis showed that the Parkelp consisted of dried kelp (seaweed); and that the tablets consisted of the same material compressed into tablet form.

The article was alleged to be misbranded in that representations in the labeling that it would be efficacious to improve the appetite, nutrition, bowel function, and skin condition; that it would be efficacious in the treatment of the hair and scalp; that it would be efficacious in secondary anemia, rickets, and other types of bone deficiency, and that it would supply adequate amounts of minerals to the diet, thus relieving colds, anemia, obesity, asthma, acidosis, mental exhaustion, rheumatism, stomach, kidney and bladder trouble, heart disorders, constipation, general debility, headaches, weakness, eczema, underweight, fatigue, glandular disturbances, goiter, thin blood, and poor circulation; and that it would be efficacious to decrease nervous irritability, increase alertness and cause marked improvement in the mental condition of dull listless children and would regulate weight and growth, were false and misleading since it would not be efficacious for such purposes.

On December 23, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

389. Misbranding of Pronto. U. S. v. 157 Packages of Pronto. Default decree of condemnation and destruction. (F. D. C. No. 3246. Sample No. 30159–E.)

The label of this product bore false and misleading representations regarding its efficacy in the conditions indicated below.

On November 4, 1940, the United States attorney for the Northern District of Illinois filed a libel against 157 packages of Pronto at Chicago, Ill., alleging that the article had been shipped in interstate commerce on or about May 8, 1940, by Alfred S. Hope from Los Angeles, Calif.; and charging that it was misbranded.

Analysis showed that the article consisted of powders, each containing bismuth subcarbonate (9.15 grains), magnesium oxide 4.22 grains), aspirin (free and combined, 3.6 grains). a silicate such as kaolin, and sugar.

The article was alleged to be misbranded in that representations in the labeling that it was efficacious in the treatment of stomach and bowel ailments, colitis, and ulcers including acute, long-standing and severe cases, duodenal ulcers, acute pains, vomiting "showing of blood" accompanying ulcers and colitis; that it would spread a thin protective film over the lining of the entire digestive canal and would heal or soothe; that it would quiet down the colon and other fretful organs, control nervousness and contractions, and restore exhausted tissues, or normal functions, were false and misleading since it was not efficacious for such purposes.

On March 7, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

390. Misbranding of Ro-Mari. U. S. v. 141 Bottles of Ro-Mari. Default decree of condemnation and destruction. (F. D. C. No. 2210. Sample No. 5990–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On June 14, 1940, the United States attorney for the Northern District of Ohio filed a libel against 141 bottles of Ro-Mari at Cleveland, Ohio, alleging that the article had been shipped in interstate commerce within the period from on or about February 17 to on or about April 1, 1940, by the American Ru-Mari Co. from Los Angeles, Calif.; and charging that it was misbranded.

Analysis showed that the article contained about 99 percent water with small proportions of potassium carbonate, sodium carbonate, sodium hydroxide, sodium chloride, sodium sulfate, and a trace of an organic compound such as chloramine T.

The article was alleged to be misbranded in that the word "Ru-Mari" which constituted a part of the firm name "American Ru-Mari Company" and appeared in the labeling, was false and misleading since it suggested that the article was a remedy for rheumatism; whereas it was not. It was alleged to be misbranded further in that its labeling bore representations that it would be efficacious to attack and correct harmful acid conditions, that it possessed effective diuretic action, and would be efficacious for arthritis, neuritis, sciatica, lumbago, gout, and allied conditions; and that it was designed to strike at the cause of pain and stiffness, and would promote elimination of toxin-forming matter through the urinary tract and was a blood conditioner, which representations were false and misleading since it was not efficacious for the purposes recommended.

On October 4, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

391. Misbranding of T-P Preparation. U. S. v. 35 Packages of T-P Preparation External and Internal. Default decree of condemnation and destruction. (F D. C. No. 2030. Sample No. 142–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated below.

On May 24, 1940, the United States attorney for the Middle District of Georgia filed a libel (amended July 13, 1940) against 35 packages of the above-named product at Valdosta, Ga., alleging that the article had been shipped in interstate commerce on or about January 26, 1940, by the Tee Pee Chemical Co. from Durham, N. C.; and charging that it was misbranded.

The article consisted of a bottle of liquid and a box of tablets. Analysis showed that the liquid consisted essentially of water, berberine sulfate, boric acid, borax, and bismuth subnitrate; and that the tablets consisted essentially of cubeb, a laxative plant drug such as cascara sagrada, ferrous carbonate, and resinous material such as Venice turpentine and copaiba.

The article was alleged to be misbranded in that the following statements, (carton) "T-P * * * Preparation External and Internal," (bottle) "T. P. * * * External Injection * * * After voidance of urine (passing water), inject small syringeful three times daily. Inject slowly and hold in urethra for several minutes. For best results use T. P. as directed for 3 or 4 weeks," and (circular) "The following directions will be found very beneficial when using T. P. Preparation: Eat very little meat; drink large quantities of water. Do not drink whiskey, wine or beer. T. P. Preparation is absolutely safe and harmless. You will be positively satisfied after using T. P. Preparation. For best results continue using T. P. Preparation for at least three or four weeks," were false and misleading since they created the impression that the article constituted a treatment for gonorrhea; whereas it did not constitute a treatment for gonorrhea.

On September 16, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

392. Misbranding of Vibratherm. U. S. v. 17 Retail Packages of Vibratherm. Default decree of condemnation and destruction. (F. D. C. No. 2176. Sample No. 4032–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On June 7, 1940, the United States attorney for the Eastern District of Michigan filed a libel against 17 packages of Vibratherm at Ferndale, Mich., alleging that the article had been shipped in interstate commerce on or about April 29 and May 10, 1940, by Vitaphore Appliances, Inc., from South Bend, Ind.; and charging that it was misbranded.

Examination showed that the device was a black plastic cylindrical applicator with electrical connections so constructed as to enable one to apply heat and vibration to any portion of the body desired.

The article was alleged to be misbranded in that its labeling contained representations that it was efficacious in the treatment of pelvic infection including endometritis, simple cervicitis, chronic proctitis, colitis, and chronic salpingitis; that it was efficacious in the treatment of prostate trouble, including nervousness, irritability, inability to sleep soundly, melancholia, pain in the crotch and rectum, frequent and painful urination, a tense feeling of the bladder and rectum, severe, intense pain in the back, loins and thighs, decreased flow of urine; that it was efficacious to dilate the blood vessels, and relax the muscles; would reduce inflammation and relieve congestion; would be efficacious to stimulate the tissues, and assist in solution of prostate gland trouble; and would be efficacious to bring satisfactory relief and comfort, which representations were false and misleading since it would not be efficacious for such purposes.

On September 16, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

393. Misbranding of Vitaphore. U. S. v. 11 Devices labeled in part "Vitaphore." Default decree of condemnation and destruction. (F. D. C. No. 2231. Sample No. 7610–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On June 20, 1940, the United States attorney for the Southern District of California filed a libel against 11 of the above-named devices at Glendale, Calif., alleging that the article had been shipped in interstate commerce on or about April 27, 1940, by Vitaphore Appliances, Inc., from South Bend, Ind.; and charging that it was misbranded.

Examination showed that the article was an electrical device so constructed as to apply vibration and heat to the body.

The device was alleged to be misbranded in that representations in the labeling that it was efficacious to improve the complexion, to maintain a skin of delicate charm and texture, to enable one to gain and retain vital health, buoyant youthfulness and glowing beauty; to soothe tired, sagging facial muscles, to strengthen and build firm tissues, to produce a youthful, healthy glow, to open the pores and penetrate dormant cells and tissues, to rejuvenate and restore at once; that it was efficacious in the treatment of headaches, incipient colds, neuritis, sinus pains, acne, scars, large pores, rough, reddened skin; that wrinkles and laughter lines would be miraculously erased; that it was efficacious in the treatment of oily skin, head colds, hay fever, skin diseases, varicose veins, asthma, backache, boils, carbuncles, bronchitis, croup, catarrh, constipation, earache, eyestrain, fatigue, falling hair, influenza, insomnia, painful or delayed menstruation, nervousness, pleurisy, pyorrhea, sciatica, stiff neck, tired feet, and pelvic and abdominal cramps, were false and misleading since it would not be efficacious for such purposes.

On August 12, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

394. Misbranding of Vitawine. U. S. v. 5⅔ Dozen Bottles of Vitawine. Default decree of condemnation and destruction. (F. D. C. No. 2531. Sample No. 5268–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On August 12, 1940, the United States attorney for the Southern District of Indiana filed a libel against 5⅔ dozen bottles of Vitawine at Indianapolis, Ind., alleging that the article had been shipped in interstate commerce on or about April 3, 1940, by Interstate Laboratories, Inc., from Louisville, Ky.; and charging that it was misbranded. The article was labeled in part: "Vitawine * * * A Vitamin B and Iron Tonic."

Analysis showed that the article contained alcohol (14.48 percent), iron and ammonium citrate (15.56 grains per fluid ounce), manganese citrate (0.63 grain per fluid ounce), and sodium citrate (5.23 grains per fluid ounce). Bio-

logical examination showed that it contained 500 International Units of vitamin B_1 per fluid ounce.

The article was alleged to be misbranded in that its labeling bore representations that it would assist in renewing health, restoring energy, enriching blood, increasing metabolism, and promoting normal growth; that it contained blood and body building ingredients; that it was indicated in any form of anemia; that it was a health tonic, ideal for those enfeebled by age and that it was efficacious in loss of appetite, nervousness, that it would provide nourishment, assist to strengthen and cleanse, restore and maintain vitality, vigor and health, tone up the intestinal tract, help prevent certain types of neuritis, prevent pellagra, inflammation of the skin, diarrhea, and mental and physical nervousness; that it was an organic revitalizer; that it would be efficacious in treating convalescents from debilitating diseases, and that it would correct sluggishness, mental fatigue, and tired worn-out feeling, which representations were false and misleading, since it would not be efficacious for such purposes.

On October 19, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

395. Misbranding of Noe's Graduated Xercisors and Massagers. U. S. v. 2 Packages each containing 14 Noe's Graduated Xercisors and Massagers. Default decree of condemnation. Product ordered delivered to welfare association. (F. D. C. No. 1977. Sample No. 1869–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On May 27, 1940, the United States attorney for the District of Columbia filed a libel against 2 packages of the above-named product at Washington, D. C., alleging that the article had been shipped in interstate commerce from Memphis, Tenn., by Roy H. Noe on or about May 22, 1940; and charging that it was misbranded. The article was labeled in part: "To T. H. Mercer c/o General Delivery Washington, D. C." It consisted of two rubber belts, one equipped with handles, an instruction book, and a circular.

The article was alleged to be misbranded in that representations in the labeling that it was the fastest waist line reducing exercise known; would build health, eliminate constipation; that it was efficacious for massaging the pelvic organs and keeping the prostate gland normal, correcting gland trouble, strengthening the eyes, building up the tissues of the air passages through the head, cutting down the chances of head colds; that it would greatly help in furthering the hearing, in relieving sinus and catarrhal trouble, in reducing weight or in gaining weight; that it would be efficacious to feed the optic nerves, correct headaches, make one think quicker and better and that it was efficacious in high blood pressure; would correct low blood pressure and would be efficacious for rheumatism and for weak lungs, which representations were false and misleading, since it would not be efficacious for such purposes.

On June 21, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a welfare organization after the destruction of the labeling.

396. Misbranding of Par-A-Pac reducing pads. U. S. v. 11 Packages of Par-A-Pac Reducing Pack and Natural Heating Pad, 7 Packages of Par-A-Pac Reducing Pack, and 10 Packages of Par-A-Pac Natural Heating Pad and Bandage. Default decree of condemnation and destruction. (F. D. C. No. 3198. Sample Nos. 14397–E, 14398–E, 14399–E.)

The labeling of these products bore false and misleading representations regarding their efficacy in the conditions indicated hereinafter.

On October 15, 1940, the United States attorney for the District of New Jersey filed a libel against the above-named products at Ventnor and Atlantic City, N J., alleging that they had been shipped in interstate commerce on or about May 21, 1940. by the Par-A-Pac Co. from New York, N. Y.; and charging that they were misbranded.

Examination showed that the devices consisted of belts or pads made up of layers of parchment, flannel, and rayon.

The articles were alleged to be misbranded in that representations in the labeling of the reducing belt that it would be efficacious for spot reducing, would reduce the waist line, abdomen, hips, thighs, legs, arms, or shoulders, would be effective to oxidize the superfluous fatty tissues and would slenderize without dieting or exercise; representations in the labeling of the reducing pack that it would be efficacious for spot reducing, would reduce the waist line, abdomen, hips, thighs, legs, arms, or shoulders, and would help throw off body toxins and waste, and

representations in the labeling of the heating pack that it would relieve congestion, chest colds, lumbago, arthritis, backache, and muscular soreness, were false and misleading since they would not be efficacious for such purposes.

On April 18, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

397. Misbranding of Redus-Aid candy. U. S. v. 250 Packages of Redus-Aid Reducing Plan and Vitadex Candy. Default decree of condemnation and sale. (F. D. C. No. 3289. Sample No. 20462–E.)

The labeling of this product bore false and misleading representations regarding its efficacy as an aid in weight reduction.

On October 25, 1940, the United States attorney for the Northern District of Georgia filed a libel against 250 packages of the above-named product at Atlanta, Ga., alleging that the article had been shipped in interstate commerce on or about September 6 and 7, 1940, by the Illinois Vitamin Products Co. from Evanston, Ill.; and charging that it was misbranded.

Analysis showed that the article consisted chiefly of sugars (including sucrose, glucose, and invert sugar), fats, proteins, and a small proportion of mineral matter including salt and a calcium compound. It had the taste and appearance of caramel candy and would furnish the same amount of calories as ordinary candy.

It was alleged to be misbranded in that statements and designs in the labeling represented and suggested that it would be efficacious to cause a loss of weight easily and sensibly, would curb the appetite for sweet, rich foods, would enable the user to cut down on the amount of food without pangs of hunger, and would help remove excess fat and increase bodily vigor, which were false and misleading since it would not be efficacious for such purposes.

On November 25, 1940, no claimant having appeared, judgment of condemnation was entered and it was ordered that the product be sold but that the boxes and literature be destroyed.

398. Misbranding of Dr. Wright's Big Four Emulsion. U. S. v. 127 Gallon Cans of Dr. Wright's Big Four Emulsion. Consent decree of condemnation. Product released under bond to be relabeled. (F. D. C. No. 1852. Sample No. 4114–E.)

The labeling of this veterinary product bore false and misleading representations regarding its efficacy in the conditions indicated below.

On or about May 10, 1940, the United States attorney for the Northern District of Illinois filed a libel against 127 gallon cans of the above-named product at Rockford, Ill., alleging that the article had been shipped in interstate commerce on or about February 24, 1940, by the Big Four Mills, Ltd., from Covington, Ky.; and charging that it was misbranded.

Analysis showed that the article was an emulsion containing fatty oils, small proportions of volatile oils (including oil of eucalyptus, ginger, and turpentine), and water.

The article was alleged to be misbranded in that the following statements in the labeling, "Dr. Wright's Big Four Emulsion for the treatment and prevention of Round and Tape worms in Chickens and Turkeys. Dr. Wright's Big Four Emulsion is non-poisonous. It will not in any way retard appetite, growth or production of the bird," were false and misleading since it would not be efficacious for the purposes recommended, namely, the treatment and prevention of round and tape worms in chickens and turkeys and against worms that infest poultry.

On November 27, 1940, Big Four Mills, Ltd., claimant, having admitted the allegations of the libel, judgment of condemnation was entered, and it was ordered that the product be released under bond conditioned that it be relabeled under the supervision of the Food and Drug Administration.

399. Misbranding of Kendall's Acute Spavin Counter-Irritant. U. S. v. 20 Bottles of Kendall's Acute Spavin Counter-Irritant. Default decree of condemnation and destruction. (F. D. C. No. 2303. Sample No. 2483–E.)

The labeling of this veterinary product bore false and misleading representations regarding its efficacy for the conditions indicated below.

On July 1, 1940, the United States attorney for the District of Massachusetts filed a libel against 20 bottles of the above-named product at Boston, Mass., alleging that the article had been shipped in interstate commerce on or about January 2 and March 25, 1940, by the Dr. B. J. Kendall Co., from Enosburg Falls, Vt.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of various oils (including thymol, camphor, oil of cloves, oil of turpentine, and oil of cade), iodine in combined form, and alcohol.

The article was alleged to be misbranded in that the carton and bottle labels bore representations regarding its efficacy in the treatment of acute bone spavin, ringbones, splints, acute irritations of the tendons (tendinitis), lameness, scratches, cracked heels, swellings, and bruises which were false and misleading since it would not be efficacious in the treatment of such conditions.

On August 6, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

400. Misbranding of I-O-Tab (Iotein Tablets). U. S. v. 1 19/24 Cases of I-O-Tab (Iotein Tablets). Default decree of condemnation and destruction. (F. D. C. No. 1948. Sample No. 13373–E.)

The labeling of this veterinary product bore false and misleading representations regarding its efficacy in the conditions indicated below.

On May 21, 1940, the United States attorney for the District of Oregon filed a libel against 1 19/24 cases of the above-named product at Portland, Oreg., alleging that the article had been shipped in interstate commerce on or about February 29, 1940, by the Dr. F. Y. Chuck Research Laboratories from San Francisco, Calif.; and charging that it was misbranded.

Analysis showed that the tablets contained 3.44 percent of nicotine and 0.85 percent of iodine incorporated in a base of feed concentrate containing crude fat (24 percent), reducing sugars, wheat starch, and tannic acid.

The article was alleged to be misbranded in that the following statements on the label and representations in an accompanying circular regarding its efficacy in the prevention and treatment of coccidiosis, blackheads and worms in general were false and misleading since it was not efficacious for the purposes recommended: (Label) "For the Treatment of Fowl Suffering from Coccidiosis, 'blackhead.' Cecum Worms (Heterakis gallina * * * I-O-Tab is Iotein in tablet form for individual treatment of pullets, hens or turkeys that have gone 'backward' or 'light' due to Chronic Coccidiosis, 'Blackhead,' * * * Cecum Worms. The active principle in I-O-Tab is Iotaline, a complex Iodo-Alkaloidal compound having a destructive action on the parasites specified, but little, if any toxic action on the fowl, when used as directed. Pick out all the birds that show the slightest sign of 'going backward' into a small pen and give each bird an I-O-Tab daily for 3–4 days. * * * help to nourish the birds back to health. A laxative should be given on the first and third days of treatment to activate the ceca in case of cecum worm infestation * * * Decided improvements should be noticed in the birds one week following treatment. Birds that have not yet responded should be treated again. For a flock treatment use Iotein."

On July 2, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS IN DECEPTIVE CONTAINERS

401. Misbranding of salicylic acid. U. S. v. 83 Cases of Salicylic Acid. Default decree of condemnation and destruction. (F. D. C. No. 1389. Sample No. 80322–D.)

The packages containing this product were filled to not more than 46 percent of their capacity.

On January 19, 1940, the United States attorney for the Eastern District of Kentucky filed a libel against 83 cases, each containing 12 one-quarter-ounce boxes of salicylic acid at Ashland, Ky., alleging that the article had been shipped in interstate commerce on or about August 2, 1939, by the George H. Nowland Co. from Cincinnati, Ohio; and charging that it was misbranded in that its containers were so made, formed, or filled as to be misleading.

On February 15, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

402. Misbranding of Zymole Trokeys. U. S. v. 71 Dozen Packages of Zymole Trokeys. Default decree of condemnation. Product ordered delivered to a Federal institution. (F. D. C. No. 3588. Sample No. 31531–E.)

This product occupied only 61.5 percent of the available space in the carton in which it was packed.

On December 23, 1940, the United States attorney for the Eastern District of Michigan filed a libel against 71 dozen packages of Zymole Trokeys at Detroit, Mich., alleging that the article had been shipped in interstate commerce on or

about November 12, 1940, by the Consolidated Drug Trade Products from Chicago, Ill.; and charging that it was misbranded in that its container was so made, formed, or filled as to be misleading.

On January 9, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a Federal institution.

403. Misbranding of moleskin adhesive plaster. U. S. v. 72 Dozen Packages of Moleskin Adhesive Plaster. Consent decree of condemnation. Product released under bond for repackaging. (F. D. C. No. 2230. Sample Nos. 30164–E, 30165–E, 30169–E, 30170–E.)

The carton containing this product was considerably larger than was necessary; approximately twice as much could have been placed in each carton.

On June 19, 1940, the United States attorney for the Northern District of Illinois filed a libel against 72 dozen packages of moleskin adhesive plaster at Chicago, Ill., alleging that the article had been shipped in interstate commerce within the period from on or about May 7 to on or about June 8, 1940, by the American White Cross Laboratories, Inc., from New Rochelle, N. Y.; and charging that it was misbranded in that its container was so made, formed, or filled as to be misleading. The article was labeled in part: "Physicians and Surgeons * * * Valentine Laboratories Inc. Distributor, Chicago."

On July 31, 1940, the American White Cross Laboratories, Inc., having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for repackaging under the supervision of the Food and Drug Administration.

NONSTERILE SURGICAL DRESSINGS

404. Misbranding of first aid kits. U. S. v. 60 Retail Packages of Sentinel Junior Ace First Aid Kits. Default decree of condemnation and destruction. (F. D. C. No. 1934. Sample No. 5241–E.)

This product had been shipped in interstate commerce and was in interstate commerce at the time of examination, at which time it was found that the cotton and gauze bandages in the kits were contaminated with micro-organisms. All items had been packed in containers which were unnecessarily large, i. e., the mercurochrome was contained in an extremely thick-walled bottle; the absorbent cotton occupied approximately one-half of the available space in the carton; the gauze bandages occupied approximately 35 percent of the available space of its carton; and the adhesive plaster occupied approximately 32 percent of the available space of its carton.

On May 14, 1940, the United States attorney for the Southern District of Indiana filed a libel against 60 retail packages of the above-named product at Indianapolis, Ind. On August 27, 1940, an amended libel was filed. It was alleged in the amended libel that the article had been shipped on or about February 15, 1940, by the McCrory Stores Corporation from New York, N. Y., and that it was misbranded.

It was alleged to be misbranded in that the statements on the label, "First Aid Kit" and "This product was thoroughly sterilized during manufacture and cleanly packaged, but continued sterility cannot be guaranteed," were false and misleading when applied to an article that was not sterile but was contaminated by micro-organisms. It was alleged to be misbranded further in that the containers were so made, formed, or filled as to be misleading.

On October 18, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

405. Misbranding of first aid kits. U. S. v. 20 Cartons of First Aid Kits. Default decree of condemnation and destruction. (F. D. C. No. 3834. Sample No. 32675–E.)

This product had been shipped in interstate commerce and was in interstate commerce at the time of examination at which time the gauze bandages and absorbent cotton were found to be contaminated with viable micro-organisms.

On February 17, 1941, the United States attorney for the Southern District of California filed a libel against 20 cartons of first aid kits at Los Angeles, Calif., alleging that the article had been shipped in interstate commerce on or about April 26, 1939, by the American White Cross Laboratories from New Rochelle, N. Y.; and charging that it was misbranded. The article was labeled in part: "White Cross Emergency First Aid Kit."

It was alleged to be misbranded in that the following statements and design appearing on the packages were false and misleading, since the bandages and cotton labeled "Absorbent Cotton" were not sterile but were contaminated with

viable micro-organisms: "The White Cross of Perfection is Your Protection. (Design of Nurse) * * * Emergency First Aid Kit. Be Prepared for Emergencies. This Handy Kit Contains Sterilized Surgical Dressings for Emergency First Aid."

On March 26, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

406. Misbranding of gauze bandage. U. S. v. 57 Cartons of Gauze Bandage. Default decree of condemnation and destruction. (F. D. C. No. 2419. Sample No. 26924–E.)

This product was contained in a carton which was 40 percent larger than was necessary; and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

On July 24, 1940, the United States attorney for the Western District of Washington filed a libel against 57 cartons of gauze bandage at Seattle, Wash., alleging that the article had been shipped in interstate commerce on or about March 12, 1940, by the American White Cross Laboratories, Inc., from New Rochelle, N. Y.; and charging that it was misbranded in that the package failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and in that the container was so made, formed, or filled as to be misleading.

On January 31, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

407. Adulteration and misbranding of gauze bandages. U. S. v. 56 Dozen and 208 Dozen Retail Packages of Non-Ravel Surgical Gauze Bandage. Default decree of condemnation and destruction. (F. D. C. No. 2820. Sample Nos. 19424–E, 19426–E.)

This product had been shipped in interstate commerce and was in interstate commerce at the time of examination at which time it was found to be contaminated with viable micro-organisms.

On September 14, 1940, the United States attorney for the Western District of Pennsylvania filed a libel against 56 dozen packages each containing 10 yards of 1-inch gauze bandage, and 208 dozen packages each containing 10 yards of 2-inch gauze bandage at Erie, Pa., alleging that the articles had been shipped in interstate commerce on or about July 3, 1940, by the Handy Pad Supply Co. from Worcester, Mass.; and charging that they were adulterated and misbranded. The article was labeled in part: "Surgical Gauze Bandage * * * Erie Drug Company."

The bandages were alleged to be adulterated in that their purity or quality fell below that which they purported or were represented to possess, namely, "Sterilized," in that they were not sterile but were contaminated with viable micro-organisms. They were alleged to be misbranded in that the following statements appearing on the cartons were false and misleading as applied to articles which were not sterile but were contaminated with viable micro-organisms: "Surgical Gauze Bandage Sterilized After Packaging Prepared Especially For The Medical Profession * * * manufactured under most sanitary conditions, for surgical use. Sterilized."

On October 15, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

408. Adulteration and misbranding of gauze bandage. U. S. v. 20 Gross Packages of Gauze Bandage. Default decree of condemnation and destruction. (F. D. C. No. 2692. Sample No. 19028–E.)

This product had been shipped in interstate commerce and was in interstate commerce at the time of examination, at which time it was found to be contaminated with viable micro-organisms. The carton was about 60 percent larger than was necessary, and the product consisted of pieces of bandage sewed together and not of a continuous strip as is expected in such a product; the roll measured less than the declared length.

On August 29, 1940, the United States attorney for the Western District of Pennsylvania filed a libel against 20 gross packages of Meditex Gauze Bandage at Pittsburgh, Pa., alleging that the article had been shipped in interstate commerce on or about June 24, 1940, by the Meditex Supply Co. from New York, N. Y.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its purity and quality fell below that which it purported or was represented to possess, namely, "Gauze Bandage Sterilized After Packing," since it did not consist of continuous strips

of gauze but of pieces sewed together; and it was not sterile but was contaminated with viable micro-organisms.

It was alleged to be misbranded in that the statements on the carton, "Gauze Bandage," "Sterilized After Packing," and "10 yds.," were false and misleading as applied to an article which did not consist of continuous strips of gauze, which was not sterile, and which was not 10 yards long, and the label of which did not reveal the fact, material in the light of the representation that the article was gauze bandage 10 yards long, that the bandage did not consist of a continuous strip but of pieces sewed together. It was alleged to be misbranded further in that the package failed to bear on its label an accurate statement of the quantity of the contents in terms of measure; and in that the container was so made, formed, or filled as to be misleading.

On September 30, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

PROPHYLACTICS

409. Action to enjoin and restrain distribution of adulterated and misbranded rubber prophylactics. U. S. v. Dean Rubber Manufacturing Co. Consent decree perpetually enjoining and restraining defendant from distributing in interstate commerce or exporting in foreign commerce rubber prophylactics. (Sample No. 10786–E.)

On August 8, 1940, the United States attorney for the Western District of Missouri filed a bill of complaint against the Dean Rubber Manufacturing Co., a corporation, North Kansas City, Mo., alleging that the defendant was engaged in the manufacture, distribution, and sale in interstate and foreign commerce of rubber prophylactics; that the said prophylactics were recommended and purported to be sold for the prevention of venereal diseases; that they were labeled variously: "Beware of social diseases. Be protected," "An aid in preventing venereal diseases," "No. 1 grade blown tested," "First Quality," and "Guaranteed two years against deterioration."

The complaint alleged further that during the period from on or about January 1 to on or about June 30, 1940, a large number of seizures had been made of prophylactics shipped in interstate commerce by the defendant which were adulterated in that their quality fell below that which they purported or were represented to possess and were misbranded in that the labeling was false and misleading.

The complaint alleged further that during the years 1938 and 1939 a large number of samples of rubber prophylactics shipped in interstate commerce by the defendant had been collected and found upon examination to contain holes.

The complaint alleged further that the defendant had on hand a large quantity of the article adulterated and misbranded as aforesaid which he contemplated introducing into interstate commerce and exporting in foreign commerce; that the prophylactics so intended for export were not in accordance with the specifications of any foreign purchaser and were misbranded and adulterated in conflict with the laws of the countries to which they were intended for export. The complaint alleged further that because of the methods of manufacture, inspection, and preparation for shipment, used by the defendant, a large percentage of faulty articles was inevitable; that the defendant had not changed its methods and had on hand for distribution in interstate and foreign commerce a large supply of defective prophylactics intended for distribution in interstate and foreign commerce.

The complaint prayed that the defendant, its officers, and its agents be perpetually enjoined from distributing in interstate commerce or shipping for export defective stock which it had on hand or might subsequently acquire. It prayed further that a temporary restraining order issue forthwith without a hearing and that, within 10 days thereafter, a hearing be held and a temporary injunction be issued to be continued until a final hearing could be had and the complainant granted a permanent injunction. On August 8, 1940, a temporary restraining order was issued in accordance with the prayer of the bill of complaint and August 15, 1940, was fixed as the date for a hearing as to why a temporary injunction should not issue.

On August 15, 1940, the defendant having consented to the entry of a decree, an injunction issued enjoining and perpetually restraining the defendant, its officers, or agents from distributing in interstate commerce or for export, except in compliance with the law, any defective prophylactic which it then had on hand at North Kansas City, Mo., or any other point, or might subsequently acquire. On September 11, 1940, the court set aside the order of

August 15, 1940, and entered an order with the same restraining provisions as the order of August 15, 1940, and defining "defective" within the meaning of the order as prophylactics which contained holes or were otherwise imperfect to the extent of making them unsuited for the prevention of venereal diseases.

410. Alleged violation of injunction. U. S. v. Dean Rubber Manufacturing Co. Defendant adjudged not guilty. (Sample No. 10786–E.)

On June 6, 1941, the United States attorney for the Western District of Missouri filed an information against the Dean Rubber Manufacturing Co., a corporation, North Kansas City, Mo., alleging that on or about November 27, 1940, the defendant shipped in interstate commerce from North Kansas City, Mo., to Omaha, Nebr., and Pittsburgh, Pa., quantities of prophylactics which were adulterated. The information further alleged that said shipments were made by the defendant wilfully, unlawfully, contumaciously and contemptuously, in violation of the injunction theretofore entered in said court, reported in notice of judgment D. D. N. J. No. 409. On the same date an order was entered that the defendant appear before the court on June 23, 1941, to show cause why it should not be punished for contempt for violation of such injunction.

On June 23, 1941, the case was heard before the court and at the completion of the evidence, the court found the defendant not guilty of wilfully and contemptuously violating the injunction.

Nos. 411 to 425 report actions based on interstate shipment of prophylactics that were defective because of the presence of holes.

411. Adulteration and misbranding of prophylactics. U. S. v. Goodwear Rubber Co., Inc., and Harry L. Ain. Plea of guilty. Corporation fined $1,000. Individual sentenced to 30 days in jail on each count. Execution of sentence on count II suspended and defendant placed on probation for 1 year to commence after having served 30 days' jail sentence on count I. (F. D. C. No. 2096. Sample No. 94913–D.)

On September 30, 1940, the United States attorney for the Southern District of New York filed an information against the Goodwear Rubber Co., a corporation, New York, N. Y., and Harry L. Ain, alleging shipment on or about November 29, 1939, from the State of New York into the State of Florida, of a quantity of prophylactics that were adulterated and misbranded.

The articles were alleged to be adulterated in that their quality fell below that which they were represented to possess in that they were represented to consist of excellent quality, air-tested, rubber prophylactics; whereas they did not consist of excellent quality, air-tested, rubber prophylactics but were defective because they contained holes. They were alleged to be misbranded in that the statements "Prophylactic Rubbers * * * Excellent Quality * * * Guaranteed 5 Years," borne on the cartons, and the statement "Air Tested" on the articles were false and misleading, since the said statements represented that the articles consisted of excellent quality, air-tested, rubber prophylactics; whereas they did not, but were defective because they contained holes.

On October 2, 1940, pleas of guilty having been entered on behalf of the defendants, the court imposed a fine of $1,000 against the corporation and sentenced the individual defendant, Harry L. Ain, to serve a sentence of 30 days in jail on count I and also 30 days in jail on count II. The sentence on the latter count was suspended and the defendant was placed on probation for 1 year to commence after serving the jail sentence on count I.

412. Adulteration and misbranding of prophylactics. U. S. v. Charles E. Jenkins, James L. Tyrrell, and Maurice Gusman (Killashun Sales Division). Pleas of guilty. Fine, $400. (F. D. C. No. 2100. Sample Nos. 3112–E, 3114–E.)

On August 12, 1940, the United States attorney for the Northern District of Ohio filed an information against Charles E. Jenkins, James L. Tyrrell, and Maurice Gusman, copartners, trading as the Killashun Sales Division, at Akron, Ohio, alleging shipment on or about August 25, 1939, from the State of Ohio into the State of Pennsylvania, of quantities of prophylactics which were adulterated and misbranded. The article was labeled in part: "Made From * * * Liquid Latex Mfg. By L. E. Shunk Latex Prod. Inc. Akron, Ohio, U. S. A."

The articles were alleged to be adulterated in that their quality fell below that which they purported or were represented to possess, in that they were represented to be disease preventives, and in that they were guaranteed to be effective for such purpose for 5 years; whereas they were not disease preventives which were guaranteed to be effective for such purpose for 5 years, since they were in whole or in part defective because of the presence of holes.

They were alleged to be misbranded in that the statements in the labeling, "For Prevention of Disease * * * Guaranteed Five Years * * * Disease Preventative Guaranteed 5 Years," were false and misleading since they represented that the articles would be effective to prevent disease and were guaranteed for such purposes for 5 years; whereas they were not effective to prevent disease and would not be effective for such purposes for 5 years since they were defective because of the presence of holes.

The information also charged other shipments of this product which were adulterated and misbranded in violation of the Food and Drugs Act of 1906, as reported in notices of judgment published under that act.

On June 18, 1941, the defendants having entered pleas of guilty, the court imposed a fine of $100 on each of the counts, the fine on the counts charging violation of the Federal Food, Drug, and Cosmetic Act amounting to $400.

413. Adulteration and misbranding of prophylactics. U. S. v. 3⅙ Gross, 285 Dozen, 18 Dozen, and 30 Dozen Prophylactics. Default decrees of condemnation and destruction. (F. D. C. Nos. 3264, 3519, 3586. Sample Nos. 10439–E, 10440–E, 10722–E, 34728–E, 34729–E.)

On October 30 and December 19 and 30, 1940, the United States attorney for the Southern District of New York filed libels against 3⅙ gross and 333 dozen prophylactics at New York, N. Y., alleging that the article had been shipped in interstate commerce on or about October 3, November 5, and December 5, 1940, by W. H. Reed & Co., Inc., from Atlanta, Ga.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its quality fell below that which it purported or was represented to possess.

It was alleged to be misbranded in that the following statements were false and misleading: (Envelope) "Three Star Brand Goldbeaters are made from choice grade of materials * * * and represent high quality of Goldbeaters * * * for the Prevention Of Disease," and (instruction sheet) "The merchandise which you will find in this package is made of selected material * * * with all the care and skill which long experience in manufacturing can give"; (carton) "Supreme * * * Specially Selected," and (envelope) "Supreme * * * Specially Selected Silver-Tex Brand Goldbeaters are made from the choicest grade of materials obtainable, * * * and represent the highest quality of Goldbeaters. * * * for the prevention of contagious diseases"; (carton) "Guaranteed Five Years," and (envelope) "Texide Brand Goldbeaters are made from the choicest grade of materials obtainable, * * * and represent the highest quality of Goldbeaters. * * * for the prevention of contagious diseases only"; and (carton) "Double Selected * * * Supreme," (envelope) 'Double Selected * * * Supreme Monat Brand Goldbeaters are made from the choicest grade of materials obtainable. * * * and represent the highest quality * * * for the prevention of contagious diseases," and (direction sheet) "* * * for the prevention of disease."

Portions of the article were alleged to be misbranded further in that it was in package form but (1) did not bear a label containing the name and place of business of the manufacturer, packer, or distributor; and (2) did not bear a label containing an accurate statement of the quantity of the contents.

On November 22, 1940, and January 8 and 17, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

414. Adulteration and misbranding of prophylactics. U. S. v. 983 Gross of Prophylactics (and 6 other seizure actions against prophylactics). Default decrees of condemnation and destruction. (F. D. C. Nos. 1314, 1315, 2430, 3160, 3624, 3645, 3671, 3676. Sample Nos. 61197–D, 61198–D, 3192–E, 10727–E, 16943–E, 19248–E, 31937–E, 31939–E, 31949–E, 31950–E, 31951–E.)

Between January 10, 1940, and January 20, 1941, the United States attorneys for the Northern District of Texas, Western District of Pennsylvania, Southern District of New York, Northern District of Illinois, and Western District of Missouri filed libels against 983 gross of prophylactics at Dallas, Tex., 11½ gross at Pittsburgh, Pa., 48 gross at New York, N. Y., 1,595 gross at Chicago, Ill., and 143 gross at Kansas City, Mo., alleging that the article had been shipped in interstate commerce by the Killashun Sales Division from Akron, Ohio, within the period from on or about March 11, 1939, to on or about December 4, 1940; and charging that it was adulterated and misbranded. The article was labeled in part variously: "Genuine LES Liquid Latex"; "Pickaniny Brand Supreme Goldbeaters * * * Olympia Lab. Atlanta, Ga."; "Diana Special * * * Distributed by Boland Laboratories, * * * New York City"; "Killian Mfg.

Co. Akron, Ohio"; "Tetratex"; "X-cello's"; "Genuine Texide"; "Silver-Tex"; "Apris"; and "Texide."

The "Genuine LES Liquid Latex" was alleged to be adulterated in that its strength fell below the professed standard or quality under which it was sold. The remaining products were alleged to be adulterated in that their quality fell below that which they purported or were represented to possess.

Misbranding was alleged in that the following statements in the labeling were false and misleading: (Genuine LES Liquid Latex) "For the prevention of disease * * * prophylactic * * * Guaranteed five years"; (Pickaniny brand) "Supreme * * * Pickaniny Brand Goldbeaters are made from choice materials and represent a high quality of Goldbeaters * * * for prevention of disease"; (Diana Special) "Special Quality"; (Tetratex) "Prophylactics * * * for prevention of venereal disease"; and (Texide) "For prevention of disease"; (X-cello's, Silver-Tex, and Apris) "Prophylactic."

Between February 23, 1940, and March 14, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

415. Adulteration and misbranding of prophylactics. U. S. v. 38 Gross of Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 3332. Sample No. 10432–E.)

On November 7, 1940, the United States attorney for the Southern District of New York filed a libel against 38 gross of prophylactics at New York, N. Y., alleging that the article had been shipped on or about October 4, 1940, by the Allied Latex Corporation from East Newark, N. J.; and charging that it was adulterated and misbranded. It was labeled in part: "Smithies."

The article was alleged to be adulterated in that its strength fell below the professed standard or quality under which it was sold, in that it was sold as and for a prophylactic and was not suitable for such purpose by reason of the fact that a large percentage contained perforations or punctures.

It was alleged to be misbranded in that the statement "Prophylactics" in the labeling was false and misleading.

On December 5, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

416. Adulteration and misbranding of prophylactics. U. S. v. 48 Gross and 11 Gross of Prophylactics. Default decree of condemnation and destruction. (F. D. C. Nos. 3622, 3623. Sample Nos. 10726–E, 10729–E.)

On January 6, 1941, the United States attorney for the Southern District of New York filed a libel against a total of 59 gross of prophylactics at New York, N. Y., alleging that the articles had been shipped in interstate commerce on or about November 20, 1940, by the Crown Rubber Sundries Co. from Akron, Ohio; and charging that they were adulterated and misbranded. They were labeled in part: "Latex Made from liquid rubber Water Cured"; or "Brevs."

The lot labeled "Latex" was alleged to be misbranded in that the statements, "Extra Quality 2 Year Guarantee * * * Guaranteed against deterioration for two years * * * for the prevention of contagious diseases," were false and misleading; and in that the label did not bear an accurate statement of the quantity of the contents. The lot labeled "Brevs" was alleged to be misbranded in that the statements, "Prophylactics * * * an aid for prevention of disease * * * new type prophylactic," were false and misleading since they were not suitable for the prevention of disease because they contained perforations and punctures; and because of their short length could not be depended upon to guard against disease.

On January 25, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

417. Adulteration and misbranding of prophylactics. U. S. v. 2¼ Gross of Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 1719. Sample No. 15386–E.)

On or about March 26, 1940, the United States attorney for the Southern District of Illinois filed a libel against 2¼ gross of prophylactics at Alton, Ill., alleging that the article had been shipped in interstate commerce on or about February 9, 1940, by Dean & Adelsperger from Kansas City, Mo.; and charging that it was adulterated and misbranded. The article was labeled in part: "Dean's Peacocks."

It was alleged to be adulterated in that its quality fell below that which it purported or was represented to possess since it was represented to be a prophylactic; whereas it was defective in that it contained holes.

It was alleged to be misbranded in that the statements in the labeling, "Peacocks are all air-blown tested—an aid in preventing venereal diseases * * * for your protection * * * No. 1 grade blown tested," were false and misleading.

On May 26, 1941, no claimant having appeared, judgment of condemnation was entered and the article was ordered destroyed.

418. Adulteration and misbranding of prophylactics. U. S. v. 10¼ Gross, 9¼ Gross, and 14 Gross of Prophylactics. Decrees of condemnation and destruction. (F. D. C. Nos. 3508, 3578. Sample Nos. 16578–E, 16579–E, 19323–E, 19333–E.)

On December 13 and 23, 1940, the United States attorneys for the District of Nebraska and the Western District of Pennsylvania filed libels against 19½ gross of prophylactics at Omaha, Nebr., and 14 gross at Pittsburgh, Pa., alleging that the article had been shipped in interstate commerce on or about November 27, 1940, by the Dean Rubber Manufacturing Co. from North Kansas City, Mo.; and charging that it was adulterated and misbranded. The article was labeled in part: "Sekurity" or "Sentinel."

It was alleged to be adulterated in that its quality fell below that which it purported or was represented to possess.

The article was alleged to be misbranded in that the following statements apearing in the labeling were false and misleading: (Sekurity brand, envelope) "Sekurity * * * Tested and Guaranteed for 2 years * * * For Use As An Aid In Preventing Venereal Diseases," (tin) "Sekurity * * * Prophylactics Sekuritys are guaranteed air blown tested. * * * An aid in preventing venereal diseases," and (stamped on article) "Air Blown Tested Sekurity"; and (Sentinel brand, tin) "Prophylactics Every Sentinel air blown tested under new testing process Finest quality * * * Beware of social diseases, be protected," (stamped on article) "Air Blown-Tested," and (circular) "Air-Blown tested * * * carefully selected and inspected Sentinel prophylactics are individually air-tested, and secure maximum protection. Unconditionally guaranteed. 'When you Ask For Sentinel You get the Best' * * * For the Prevention of Disease."

On January 16, 1941, no claimant having appeared for the product seized at Pittsburgh, and on March 6, 1941, the claimant for the product seized at Omaha having consented to the entry of a decree, judgments of condemnation were entered and the product was ordered destroyed.

419. Misbranding of prophylactics. U. S. v. 49 Gross of Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 1668. Sample No. 1049–E.)

On March 22, 1940, the United States attorney for the Western District of Virginia filed a libel against 49 gross prophylactics at Danville, Va., which had been consigned by Gotham Sales Co., Inc., alleging that the article had been shipped in interstate commerce on or about January 10, 1940, from New York, N. Y.; and charging that it was adulterated in that its strength fell below the professed standard of quality under which it was sold. It was labeled in part: "Crescent."

On September 4, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

420. Adulteration and misbranding of prophylactics. U. S. v. 6 Gross of Prophylactics (and 7 other seizure actions against prophylactics). Default decrees of condemnation and destruction. (F. D. C. Nos. 2544, 2708, 2729, 2791, 2810, 2998, 3149, 3197. Sample Nos. 4076–E, 16158–E, 18004–E, 19217–E, 19247–E, 27449–E, 27562–E, 30906–E.)

Between August 14 and October 12, 1940, the United States attorneys for the Western District of Pennsylvania, Northern District of Illinois, Southern District of Indiana, Western District of Missouri, Northern District of Ohio, Eastern District of Michigan, and Northern District of Alabama, filed libels against 11 gross 5½ dozen prophylactics at Pittsburgh, Pa.; 9¼ gross of the product at Chicago, Ill.; 8¼ gross at Indianapolis, Ind.; 13 gross at Kansas City, Mo.; 5⅔ gross at Cleveland, Ohio; 6¼ gross at Detroit, Mich.; and 4 gross at Birmingham, Ala., alleging that the article had been shipped in interstate commerce within the period from on or about July 8 to on or about August 31, 1940, by the Eveready Trading Co. from New York, N. Y., and Newark and East Newark, N. J.; and charging that it was adulterated and misbranded. It was labeled in part: "Beacon Tips. * * * Beacon Sundries, Inc., New York City."

The article was alleged to be adulterated in that its quality fell below that which it purported or was represented to possess.

It was alleged to be misbranded in that representations in the labeling regarding its efficacy as a protection against infection were false and misleading.

Between September 9 and December 7, 1940, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

421. Adulteration and misbranding of prophylactics. U. S. v. 19 Dozen Prophylactics and 76 Dozen Prophylactics. Default decree of destruction. (F. D. C. Nos. 4870, 4871. Sample Nos. 43433–E, 43434–E.)

On June 9, 1941, the United States attorney for the Northern District of Oklahoma filed a libel against 19 dozen animal membrane prophylactics and 76 dozen rubber prophylactics at Tulsa, Okla., alleging that the articles had been shipped in interstate commerce on or about April 11, 1941, by International Distributors from Memphis, Tenn.; and charging that they were adulterated and misbranded. The rubber prophylactics were labeled in part: "Rough Rider."

The articles were alleged to be adulterated in that their quality fell below that which they purported or were represented to possess.

The animal membrane prophylactics were alleged to be misbranded in that they were in package form and the label did not bear the name and place of business of the manufacturer, packer, or distributor; and in that they were in package form and the label did not bear an accurate statement of the quantity of contents.

The rubber prophylactics were alleged to be misbranded in that the statement "for prevention of disease," which appeared on the 1-gross carton, the 1-dozen carton, and the 3-unit carton, and was stamped on the article, was false and misleading.

On June 27, 1941, no claimant having appeared, judgment was entered ordering that the products be destroyed.

422. Adulteration of prophylactics. U. S. v. 30 Gross of Rubber Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 2249. Sample No. 10694–E.)

On June 24, 1940, the United States attorney for the District of Connecticut filed a libel against 30 gross of prophylactics at New Haven, Conn., alleging that the article had been shipped in interstate commerce on or about May 27, 1940, by the National Latex Products Corporation from East Newark, N. J.; and charging that it was adulterated in that its quality fell below that which it purported or was represented to possess. The article was labeled in part "Silk-Tex."

On September 20, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

423. Adulteration and misbranding of prophylactics. U. S. v. 3 7/12 Gross of Prophylactics (and 2 other seizure actions against prophylactics). Default decrees of condemnation and destruction. (F. D. C. Nos. 2988, 3271, 3533. Sample Nos. 14997–E, 20147–E, 46322–E.)

This product was not only defective because of the presence of holes, but its label failed to bear certain information required by the law as indicated hereinafter.

On September 16, October 23, and December 18, 1940, the United States attorneys for the Middle District of Pennsylvania and the Middle District of Georgia filed libels against 3 7/12 gross of prophylactics at Williamsport, Pa.; 35 gross at Scranton, Pa.; and 3 6/12 gross at Dixie, Ga., alleging that the article had been shipped in interstate commerce within the period from August 22 to on or about October 10, 1940, by the Penn Jersey Drug Co. from Newark, N. J.; and charging that it was adulterated and misbranded. A portion of the article was labeled in part: "Sanytex." The remainder was labeled in part: "Saf-T-Skin * * * Gotham Rubber Co. Chicago New York."

The article was alleged to be adulterated in that its quality fell below that which it purported or was represented to possess. It was alleged to be misbranded in that the following statements appearing on the labeling were false and misleading: (Sanytex) "Disease Preventative," "Select Quality," "Unlimited Guarantee Against Deterioration," and "For Prevention of Disease"; (Saf-T-Skin) "The Dependable Prophylactic Saf-T-Skin * * * to prevent disease Guaranteed Five Years." The Sanytex brand was alleged to be misbranded further in that its label did not bear the name and address of the manufacturer, packer, or distributor. The Saf-T-Skin brand was alleged to be misbranded further in that its label did not bear an accurate statement of the quantity of the contents.

On November 2 and 18, 1940, and February 20, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

424. Adulteration and misbranding of prophylactics. U. S. v. 13 Gross of Rubber Prophylactics. Default decree of condemnation and destruction. (F. D. C. No. 2687. Sample No. 20099–E.)

On August 29, 1940, the United States attorney for the Western District of South Carolina filed a libel against 13 gross of prophylactics at Spartanburg, S. C., alleging that the article had been shipped in interstate commerce on or about July 26, 1940, by W. H. Reed & Co., Inc., from Atlanta, Ga.; and charging that it was adulterated and misbranded. It was labeled in part "Golden Pheasant."

The article was alleged to be adulterated in that its quality fell below that which it purported or was represented to possess.

It was alleged to be misbranded in that the following statements on the labeling were false and misleading: (Tin) "Prophylactics," and (stamped on article) "Guaranteed."

On October 2, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

425. Adulteration and misbranding of prophylactics. U. S. v. 2 7/12 Gross and 59 Gross of Prophylactics. Default decrees of condemnation and destruction. (F. D. C. Nos. 2388, 2428. Sample Nos. 3191–E, 10843–E.)

On July 19 and 26, 1940, the United States attorneys for the Western District of Pennsylvania and the Southern District of New York filed libels against 2 7/12 gross of prophylactics at Pittsburgh, Pa., and 59 gross of prophylactics at New York, N. Y., alleging that the article had been shipped in interstate commerce on or about May 22 and June 26, 1940, by the Rubber Research Products Corporation from Jersey City, N. J.; and charging that it was adulterated and misbranded. It was labeled in part "Kaps."

The article was alleged to be adulterated in that its quality fell below that which it purported or was represented to possess.

It was alleged to be misbranded in that the statements, "It is a limited but valuable Aid, though Not an Entire preventive, against venereal infection," borne on the packages and similar statements in a leaflet contained in the package, were false and misleading.

On August 19 and September 25, 1940, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 326–425

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] Contains instructions to the jury.
[2] Contains an opinion of the court.
[3] Permanent injunction issued.
[4] Alleged violation of injunction.

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U. S. GOVERNMENT PRINTING OFFICE: 1942

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

426–540

DRUGS AND DEVICES

The cases reported herewith, commenced prior to June 30, 1940, were instituted in the United States District Courts by the United States attorneys acting upon reports submitted by direction of the Secretary of Agriculture; and those commenced on and after that date were similarly instituted upon reports submitted by direction of the Federal Security Administrator.

PAUL V. MCNUTT, *Administrator, Federal Security Agency.*

Washington, D. C., July 29, 1942.

CONTENTS [1]

[1] See pages 216, 218, 220, 221, 224, and 229 (D. D. N. J. Nos. 433, 436, 437, 439, 443, and 451) for failure to bear name and place of business of manufacturer, packer, or distributor.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

426. Adulteration and misbranding of Catawba's Nervine and Acetandyne Pain Tablets; misbranding of Black Tablets for Kidneys, Bladder, and Uretes, Catawba's Bu-Q-Ju Diuretic, Catawba's Pep-A-Man Tonic Laxative, and Nu-Vig-Or Laxative-Tonic. U. S. v. William B. Goebel (Botanical Medicine Co.). Plea of guilty. Fine, $100. (F. D. C. No. 2906. Sample Nos. 340–E, 341–E, 20232–E to 20235–E, incl.)

Catawba's Nervine would be dangerous to health when used according to directions in the labeling, and its labeling also failed to bear adequate directions for use. Adequate warning statements did not appear in the labeling of the Nervine and of the Acetandyne Pain Tablets. These two products also failed to meet their own standards of strength and quality, the Nervine was falsely labeled as a safe treatment for certain conditions, and the other products all bore false and misleading therapeutic claims.

On March 28, 1941, the United States attorney for the Middle District of North Carolina filed an information against William B. Goebel, trading as Botanical Medicine Co., Kannapolis, N. C., alleging shipment on or about June 7 and 10, 1940, from the State of North Carolina into the States of Virginia and South Carolina of a quantity of the above-named products, of which a portion were misbranded and the remainder were adulterated and misbranded.

Analysis of a sample of Catawba's Nervine showed that it contained not more than 3.97 grains of sodium bromide per ⅛ fluid ounce, not more than 3.7

grains of potassium bromide per ⅛ fluid ounce, and not less than 0.93 grain of ammonium bromide per ⅛ fluid ounce. It was alleged to be adulterated in that its strength differed from or its quality fell below that which it purported or was represented to possess since it was represented to contain 4½ grains of sodium bromide, 4½ grains of potassium bromide, and ½ grain of ammonium bromide in each ⅛ fluid ounce; whereas it contained not more than 3.97 grains of sodium bromide, not more than 3.7 grains of potassium bromide, and not less than 0.93 grain of ammonium bromide. It was alleged to be misbranded: (1) In that the statement on the label, "Each teaspoonful (⅛ oz.) Contains Sodium Bromide 4½ gr. Potassium Bromide 4½ gr. Ammonium Bromide ½ gr.," was false and misleading. (2) In that the bottle label represented and suggested that it constituted a safe and appropriate treatment for the conditions mentioned thereon; whereas it was a dangerous drug and the labeling failed to reveal the material fact that its use under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual, i. e., the use of the drug in accordance with the directions, might lead to mental derangement. (3) In that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, "Adult dose—Take one teaspoonful in half glass of water. If necessary repeat but do not take over four teaspoonfuls in any twenty-four hour period." (4) In that its labeling failed to bear adequate directions for use. (5) In that its labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users.

Analysis of a sample of Black Tablets for the Kidneys, Bladder, and Uretes showed that they contained compounds of magnesium and aluminum, cubeb, copaiba, methyl salicylate, and sugar. They were alleged to be misbranded in that the statement in the labeling, "For The Kidneys Bladder and Uretes," was false and misleading since it represented that the drug was efficacious in the treatment of disorders of the kidneys, bladder, and uretes (ureter); whereas it was not efficacious for such purposes.

Analysis of a sample of Catawba's Bu-Q-Ju Diuretic showed that it consisted essentially of extracts of plant drugs (including cubeb and peppermint), sugar, alcohol, and water. It was alleged to be misbranded in that the statement in the labeling, "aids the elimination of the toxic poisonous substances," was false and misleading since the drug was not efficacious for that purpose.

Analysis of a sample of the Acetandyne Pain Tablets showed that they contained not more than 0.99 grain of acetanilid and not less than 2.79 grains of aspirin per tablet. They were alleged to be adulterated in that their strength differed from or their quality fell below that which they purported or were represented to possess since each tablet was represented to contain 2 grains of acetanilid and 1 grain of aspirin; whereas each of the tablets contained not more than 0.99 grain of acetanilid and not less than 2.79 grains of asipirin. They were alleged to misbranded in that the statement, (carton) "Acetandyne Pain Tablets This preparation contains Acetanilid 2 gr. Aspirin 1 gr.," was false and misleading. They were alleged to be misbranded further (1) in that the labeling failed to bear adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users; and (2) in that the statement in the labeling, "Pain Tablets * * * pains caused by menstrual disturbances * * * Menstrual pains," was false and misleading since it represented that the drug was efficacious in the treatment of pains caused by menstrual disturbances; whereas they were not efficacious for such purposes.

Analysis of a sample of Nu-Vig-Or showed that it contained plant material including cloves, capsicum, an emodin-bearing drug such as senna, and a bitter principle such as gentian, sulfur, sodium sulfate, magnesium carbonate, and sodium bicarbonate. It was alleged to be misbranded in that the statement in the labeling, "Nu-Vig-Or * * * Tonic Nu-Vig-Or is a tonic," was false and misleading since it represented that the drug would supply new vigor and would restore vigor; whereas it was not efficacious for such purposes.

Analysis of a sample of Catawba's Pep-A-Man Tonic Laxative showed that it contained extracts of plant drugs including a laxative drug, aloin, and strychnine sulfate. It was alleged to be misbranded in that the statement in the labeling, "Pep-A-Man Tonic," was false and misleading since it represented that the drug possessed tonic properties and the restorative, vitalizing, and invigorating

properties implied in the name "Pep-A-Man"; whereas it did not possess such properties.

On April 21, 1941, the defendant entered a plea of guilty and the court imposed a fine of $100 and placed the defendant on probation for 3 years.

427. Misbranding of Hillman's D Compound. U. S. v. David Hillman (Hillman Pharmaceutical Co.). Plea of guilty. Fine, $1 and costs. (F. D. C. No. 2866. Sample No. 4610–E.)

On November 15, 1940, the United States attorney for the Northern District of Illinois filed an information against David Hillman, trading as Hillman Pharmaceutical Co., Chicago, Ill., alleging shipment on or about February 5, 1940, from the State of Illinois into the State of Wisconsin of a quantity of Hillman's D Compound which was misbranded.

Analysis of a sample of the article showed that the capsules each contained aminopyrine (1.44 grains), a small proportion of ephedrine sulfate, and milk sugar, flavored with peppermint oil.

The article was alleged to be misbranded (1) in that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling; (2) in that its labeling did not bear adequate directions for use; (3) it did not bear adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users. It was alleged to be misbranded further in that the labeling was false and misleading since it created the impression that the article constituted a safe and appropriate treatment for the conditions mentioned in the labeling; whereas it did not constitute a safe and appropriate treatment for the conditions mentioned in the labeling, but was a dangerous drug, and the labeling failed to reveal the material fact that this drug might cause serious blood disturbances. It was alleged to be misbranded further in that statements in the labeling representing that it would be efficacious in the treatment of dysmenorrhea (painful menstruation), would be efficacious in the treatment of cramps, backache, and headache which accompany menstruation, and would banish painful menstruation, were false and misleading since it would not be efficacious for such purposes.

On December 18, 1940, the defendant entered a plea of guilty and the court imposed a fine of $1 and costs.

428. Misbranding of Young's Preparation. U. S. v. Oscar Lee Brunson. Plea of guilty. Defendant placed on probation for 3 years. (F. D. C. No. 2931. Sample Nos. 537–E, 20701–E.)

This product would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, in which it was recommended for the relief of itching skin and scalp and which contained directions that it should be well shaken and applied to afflicted parts two or three times a day; that if the parts were raw, it should be diluted with water until it could be used full strength and that it was natural for the drug to sting when first applied.

On March 11, 1941, the United States attorney for the Southern District of Georgia filed an information against Oscar Lee Brunson of Waycross, Ga., alleging shipment on or about March 4 and May 31, 1940, from the State of Georgia into the State of Florida, of quantities of Young's Preparation which was misbranded for the reasons appearing above.

The article was also alleged to be misbranded in violation of the Federal Caustic Poison Act, as reported in Notice of Judgment No. 105 published under that act.

On June 16, 1941, a plea of guilty having been entered, the defendant was placed on probation for 3 years.

429. Adulteration and misbranding of B-D-Mint Powders. U. S. v. 55 Cards of B-D-Mint Powders. Default decree of condemnation and destruction. (F. D. C. No. 3389. Sample No. 28215–E.)

This product would be dangerous to health when used as directed in the labeling and was not labeled to indicate the consequences that might result from its use. Its labeling also bore false and misleading representations regarding its curative and therapeutic efficacy and was further objectionable as indicated below.

On or about November 20, 1940, the United States attorney for the Western District of Virginia filed a libel against 55 cards, each carrying 28 envelopes

of B-D-Mint Powders, at Pulaski, Va., alleging that the article had been shipped in interstate commerce by South Bluefield Pharmacy, Inc., from Bluefield, W. Va., on or about October 25, 1940; and charging that it was adulterated and misbranded. The article was labeled in part: "Prepared By B. D. Medicine Co., Pulaski, Va."

Analysis showed that the powders each contained approximately 3.83 grains of acetophenetidin, 2.23 grains of acetanilid, 1.5 grains of citrated caffeine, and 3.6 grains of sodium bicarbonate, together with milk sugar and sweetened with saccharin and flavored with peppermint oil.

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, since the envelope was labeled, "Not Over 2½ Grains Each Acetanilid Acetophenetidin"; whereas each powder contained materially more than 2½ grains of acetophenetidin.

It was alleged to be misbranded in that the statements on the display card, "No Harmful Ingredients," "Safe," "No After Effect," and the designation "B–D–Mint" were false and misleading since it contained potentially harmful ingredients, was not free from danger, might cause serious aftereffects, and the principal active ingredients were not derived from mint.

It was alleged to be misbranded further in that the statements, (envelope) "Quick Relief For the Pain and Discomfort Arising From Simple Headache Neuralgia Muscular Aches and Pains Head Colds and as Nerve Sedative," "For * * * Female Pains, Muscular Aches and Pains, Simple Head Colds, for Reducing Fever, as Nerve Sedative," and (display card) "Quick Relief For the Pain and Discomfort Arising from Simple Headache Neuralgia Rheumatism Earache Toothache," "Headache Head Colds * * * Neuralgia Nerve Sedative * * * Muscular Aches and Pains," were false and misleading since it was not an adequate treatment for the various conditions mentioned and because of failure of the label to reveal the material fact that its use in such conditions might cause ill effects.

It was alleged to be misbranded further in that the statement in the labeling, "Prepared by B. D. Medicine Co., Pulaski, Va.," was false and misleading since it was prepared by South Bluefield Pharmacy, Inc., Bluefield, W. Va. It was alleged to be misbranded further in that its label failed to bear the common or usual name of each of the active ingredients together with the statements of the quantity or proportion of acetanilid and acetophenetidin since the statement on the label, "Not Over 2½ Grains Each Acetanilid Acetophenetidin," was not such a statement and was not true in fact.

It was alleged to be misbranded further in that the package failed to bear a statement of the quantity of the contents; and in that its labeling failed to bear adequate directions for use since the directions appearing on the envelope, "Take one powder * * * may repeat in one hour if not relieved. After second dose, not oftener than every 2 or 3 hours. If not relieved, after four or five doses consult your doctor. Children over 8 years old: One-fourth powder. May repeat in 2 or 3 hours," were not suitable and appropriate directions for the use of the article.

It was alleged to be misbranded further in that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; and in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, and suggested in the labeling.

On May 16, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

430. Misbranding of Bromo-Thein. U. S. v. 48 Bottles of Bromo-Thein. Default decree of condemnation and destruction. (F. D. C. No. 3943. Sample No. 31586–E.)

This product consisted essentially of acetanilid, bromides (such as sodium bromide and potassium bromide), aspirin, caffeine, sodium bicarbonate, citric acid, and tartaric acid. It would be dangerous to health when used as recommended and its labeling failed to reveal the consequences which might result from its use and failed in other respects as indicated hereinafter to comply with the labeling requirements of the law.

On March 10, 1941, the United States attorney for the Eastern District of Michigan filed a libel against 48 bottles of Bromo-Thein at Detroit, Mich., alleging that the article had been shipped in interstate commerce on or about

February 8, 1941, by Lockwood Laboratories from Hammond, Ind.; and charging that it was misbranded.

The article was alleged to be misbranded in that the statement of active ingredients, the directions for use, and the warning appearing upon the label were not prominently placed thereon with such conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the statement "Chester A. Lockwood" diagonally written across these statements tended to obscure them.

It was alleged to be misbranded further in that the label failed to bear adequate directions for use, since they did not provide for a limit as to duration or frequency of administration.

It was alleged to be misbranded further in that the label failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form, as were necessary for the protection of users, since there was no warning that the frequent or continued use of acetanilid might be dangerous, causing serious blood disturbances, anemia, collapse, or a dependence on the drug, and that frequent or continued use of bromides might lead to mental derangement, skin eruptions, or other serious effects. (The preparation, when taken according to directions, would permit the administration of 6.84 grains of acetanilid daily.)

The article was alleged to be misbranded further in that it was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof, namely: "Dose: a heaping teaspoonful in half glass of water; if not relieved repeat after interval of four hours, not to exceed three doses in twenty-four hours."

On April 3, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

431. Misbranding of Casey's Compound. U. S. v. 329 Bottles of Casey's Compound. Default decree of condemnation and destruction. (F. D. C. No. 4004. Sample No. 60029-E.)

On March 29, 1941, the United States attorney for the District of Oregon filed a libel against the above-named product at Portland, Oreg., alleging that it had been shipped on or about February 12, 1941, by the Geo. E. Madison Co. from San Francisco, Calif.; and charging that it was misbranded.

Analysis of a sample of the article showed that it contained potassium iodide (19.8 grains per fluid ounce) in a flavored syrup.

The article was alleged to be misbranded: (1) In that it would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling. (2) In that the label failed to bear adequate directions for use since the directions (bottle and carton) "One-half teaspoonful in half a glass of water, one hour after each meal for four days; then gradually increase to one full teaspoonful over 4 days time and continue the dose of one teaspoonful. This is the usual dose but may be increased to double the amount," were not adequate. (3) In that its labeling failed to bear adequate warnings against use where its use might be dangerous to health or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users. (4) In that statements in a leaflet entitled "Casey's Compound," supplied in response to a request by postcard enclosed in the retail package, representing that it would be efficacious for the relief of arthritis, neuritis, rheumatism, and sciatica; and that its use would make the purchaser's general health much better, and enable him to enjoy a good night's rest, were false and misleading since it would not be efficacious for such purposes.

On June 4, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

432. Misbranding of Cold Special No. 2 Red. U. S. v. 1 Bottle and 18 Bottles of Cold Special Capsules (and 2 other seizures of Cold Special Capsules). Default decrees of condemnation and destruction. (F. D. C. Nos. 3873 to 3875, incl. Sample No. 50059-E.)

On February 26, 1941, the United States attorney for the District of Columbia filed libels against 1 bottle containing 2,800 Cold Special Capsules, 1 bottle containing 25 capsules, and 65 bottles containing 12 capsules at Washington, D. C., alleging that they were being offered for sale in the District of Columbia—1 large bottle and 18 small bottles at Albany Pharmacy, 1 large bottle

and 16 small bottles at the Southern Drug Co., and 31 small bottles at National Press Pharmacy; and charging that they were misbranded. The articles were labeled in part: "Capsules Cold Special * * * [or "Cold Special * * * Each Capsule Contains:"] * * * Dose: One capsule every hour as required [or "Directions One Capsule every 2 or 3 hours * * * Notice—Acetanilid is a dangerous drug, over dosage may cause depression of the heart or circulatory system" or "Dosage Adults: 1 capsule every hour until 4 or 5 have been taken, then 1 capsule every three hours as required * * * Acetanilid preparation may depress the heart and should not be taken continuously except under the direction of a physician"]."

Analysis of a sample of the article showed that each capsule contained acetanilid (approximately 2 grains), quinine sulfate (approximately ½ grain), camphor, podophyllin, and aloin.

The article was alleged to be misbranded (1) in that it would be dangerous to health when used in the dosage or with the frequency and duration prescribed, recommended, and suggested in the labeling; (2) in that the labeling failed to bear adequate directions for use since the directions appearing thereon were inappropriate for an article of the composition of this one; (3) in that the labeling failed to bear an adequate warning against use in those pathological conditions and by children where its use might be dangerous to health, or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users; and (4) in that the designation "Cold Special," appearing on the labeling, was false and misleading since the article did not constitute a treatment or preventive for the disease condition commonly known as "cold."

On May 20, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

433. Misbranding of Halomist Sets and Refills. U. S. v. 89 Packages of Halomist Sets and 100 Bottles of Halomist (and 1 other seizure of Halomist and Halomist Refills). Default decrees ordering destruction of the products. (F. D. C. Nos. 4347, 4872. Sample Nos. 53047–E, 53048–E, 58037–E, 58038–E.)

This product, in addition to being potentially dangerous when used according to directions, bore false and misleading therapeutic claims in its labeling and also failed to comply with certain other labeling provisions of the law.

On May 27 and June 6, 1941, the United States attorneys for the Southern District of California and the District of Minnesota filed libels against 89 packages (each package containing an applicator, medicine dropper, and a bottle of Halomist) and 100 bottles of Halomist at Los Angeles, Calif., and 11 Halomist Sets, 27 1-ounce and 4 half-ounce Halomist Refills at Minneapolis, Minn., alleging that the article had been shipped by Halomist, Inc., from Seattle, Wash., within the period from on or about March 19 to on or about April 21, 1941; and charging that it was misbranded.

Analyses of samples showed that the Halomist consisted essentially of racemic epinephrine hydrochloride (in one sample, 2.3 grams, in the other, 2.4 grams per 100 cubic centimeters), chlorobutanol, and water.

The article was alleged to be misbranded: (1) In that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, which recommended that it be used at least 3 times daily—with inhalations of 15 to 35 minutes' duration and in extreme cases, of 45 minutes' to 2 hours' duration. (2) In that statements in the labeling that it would be efficacious for the relief of paroxysms of bronchial asthma, for treatment of hay fever or sinusitis; that it would be efficacious to prevent asthma attacks, to build up natural resistance and strength and to build up weight; that the user would be able to eat what he pleased; that it would be soothing to the membranes; that it contained an ideal antiseptic for the sinuses; that it would build up resistance against sinus disorders and catarrhal conditions; and that it would toughen the tissues against infection and irritation, were false and misleading since it was neither a safe nor an appropriate treatment for the conditions named. (3) In that the carton containing the set did not bear the common or usual names of the active ingredients nor a statement of the quantity or proportion of chlorobutanol present. (4) In that the name and address of the manufacturer was not prominently placed on the carton with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read by the ordinary individual under cus-

tomary conditions of purchase and use. (5) In that the carton containing the set did not bear an accurate statement of the quantity of contents.

On June 24 and September 25, 1941, no claimant having appeared, judgments were entered ordering that the product be destroyed.

434. Misbranding of Happy Day Headache Powders. U. S. v. 21½ Gross Packages of Happy Day Headache Powders. Default decree of condemnation and destruction. (F. D. C. No. 4008. Sample No. 50903-E.)

This product would be dangerous to health when used according to directions, its labeling failed to bear adequate directions for use and warning statements, and in addition it bore false and misleading therapeutic claims.

On or about March 21, 1941, the United States attorney for the Western District of Virginia filed a libel against 21½ gross packages of Happy Day Headache Powders at Roanoke, Va., alleging that the article had been shipped from Winston-Salem, N. C., in part in the personally owned automobile of Max Caplan, owner of the Capital Drug Co., Roanoke, Va., on or about September 16, 1940, and in part by the Sessions Specialty Co. on or about November 8, 1940; and charging that it was misbranded. It was labeled in part: "Happy Day Headache Powders * * * Manufactured by Gulf Laboratories Inc. Lafayette Louisiana."

Analyses of samples of the article showed that it consisted essentially of acetanilid (2½ grains per powder), aspirin, caffeine, phenolphthalein, and milk sugar.

The article was alleged to be misbranded: (1) In that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely, (envelope containing powder) "Directions Take one powder dry on the tongue followed with water, or mixed with a little water. One powder usually gives the desired results. If necessary, another powder may be taken in 30 minutes. Women will find this especially beneficial during painful menstrual periods"; (circular) "Take one powder dry on the tongue, followed by a swallow of water, or mix well with small quantity of water and take. Repeat in 20 minutes if necessary. One powder usually gives relief. Children over 6 years: ¼ to ½ of one powder. * * * One powder well mixed in a little water at the first sign of cold or fever and one two hours later. One powder at night just before retiring is recommended. Children over six years: ½ powder mixed in water 3 times daily according to age. * * * One powder dissolved in water every 2 or 3 hours as required." (2) In that the labeling failed to bear adequate directions for use. (3) In that the labeling did not bear such adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users. (4) In that statements in the labeling representing that it would be efficacious for the relief of discomfort arising from head colds, hay fever, and nervousness; that it would reduce fever, insuring speedy relief; that it would be efficacious for the relief of pains caused by menstrual disturbances, tonsillitis, headache caused by sinus trouble, rheumatism, influenza, and throat irritations, were false and misleading since it would not be efficacious for such purposes. (5) In that the label did not bear the common or usual names of the active ingredients. (6) In that the label did not bear an accurate statement of the quantity of contents.

On July 15, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

435. Misbranding of Suppletive Formula Number 1, Supportive Formula S. G. M. a, and Formula No. 1. U. S. v. 326 Ampuls of Suppletive Formula Number 1, 88 Ampuls of Supportive Formula S. G. M. a, and 2 Bottles of Formula No. 1. Default decrees of condemnation and destruction. (F. D. C. Nos. 3318, 3548, 3549. Sample Nos. 30843-E, 31909-E, 31912-E.)

Examination of Suppletive Formula Number 1 disclosed that it contained emetine hydrochloride. This product would be dangerous to health when used in the dosage suggested in the labeling. Its label and that of Formula No. 1 failed to bear such warnings as might be necessary for the protection of users. All three products failed to bear adequate directions for use and to name the active ingredients present.

On November 16 and December 20, 1940, the United States attorney for the Northern District of Illinois filed libels against the above-named products at

Chicago, Ill., alleging that the articles had been shipped in interstate commerce on or about May 3 and October 17, 1940, by the E. S. Miller Laboratories, Inc., from Los Angeles, Calif.; and charging that they were misbranded. The articles were labeled in part: "Suppletive Formula Number 1 [or "Supportive Formula S. G. M. a"] Specially prepared for the Samaritan Treatment"; or "Formula No. 1 Manufactured for The Samaritan Treatment."

Analyses showed that the Supportive Formula consisted essentially of glandular material and water; and that Formula No. 1 consisted essentially of compounds of ephedrine, pilocarpine, emetine, and strychnine, sulfates and chlorides, and water.

The Suppletive Formula Number 1 was alleged to be misbranded in that it would be dangerous to health when used in the dosage suggested in its labeling. This product and Formula No. 1 both were alleged to be misbranded in that their labeling failed to bear adequate warnings against use in those pathological conditions (or by children in the case of Formula No. 1) where their use might be dangerous to health or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for protection of users.

All three products were alleged to be misbranded (1) in that their labeling failed to bear adequate directions for use; and (2) in that they were fabricated from two or more ingredients and their labeling failed to bear the common or usual names of their active ingredients.

On January 28 and March 3, 1941, no claimant having appeared, judgments of condemnation were entered and products were ordered destroyed.

436. Adulteration and misbranding of Sterile Uteroids, Prevent-All, Leucorrhea Special No. 9; misbranding of Gleet Specific, Argosine, Picricine, Prostatic Depletent, Prostatic Absorbent, and Aesculus Pile Cerate. U. S. v. 94 Cartons and 125 Tubes of Sterile Uteroids, 10 Cartons of Prevent-All, 94 Cartons of Leucorrhea Special No. 9, 34 Packages of Gleet Specific, 117 Cartons of Argosine, 126 Cartons of Picricine, 23 Cartons of Prostatic Depletent, 21 Cartons of Prostatic Absorbent, and 23 Cartons of Aesculus Pile Cerate. Default decrees ordering destruction. (F. D. C. Nos. 3370 to 3374, incl., 3376, 3378, 3501 to 3503, incl. Sample Nos. 16393–E to 16397–E, incl., 16399–E, 16901–E, 16913–E to 16915–E, incl.)

Adequate directions for use were not borne on the labels of Leucorrhea Special No. 9; the labeling of Picricine and Aesculus Pile Cerate failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; the labeling of all the other products except Prevent-All failed to bear adequate directions for use and adequate warning statements. The Sterile Uteroids, Prevent-All, and Leucorrhea Special No. 9 were adulterated because their strength differed from and their quality fell below that which they purported or were represented to possess. All of the products except Picricine and Argosine bore false and misleading statements regarding their ingredients or their therapeutic properties. The labels on the immediate container (collapsible tube) of the repackaged portion of Leucorrhea Special No. 9, the labeled portion of Argosine (and the cartons of the remainder of these two products), and of all the other products failed to bear the common or usual name of each of their active ingredients.

The packages of all the products (and the cartons in the case of the unlabeled portion of Argosine and the portion of Leucorrhea Special No. 9 that had not been repackaged) failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, since the immediate container (collapsible tube) carried no label; and the name and address Ainsworth Specialty Co., Kansas City, Mo., appearing on the carton were not those of the manufacturer, and were not qualified by a phrase which revealed the connection the firm mentioned had with the drugs. The packages of all the products (the immediate container (collapsible tube) of the labeled portion of Argosine and of the repackaged portion of Leucorrhea Special No. 9, and the cartons containing the unlabeled portion of Argosine and the portion of Leucorrhea Special No. 9 that had not been repackaged) failed to bear the required quantity of contents statement.

On or about November 23 and December 20, 1940, the United States attorney for the Western District of Missouri filed libels against the above-named products at Kansas City, Mo., alleging that the articles had been shipped by C. F. Breitenbach (Mucine Co.) from Chicago, Ill., within the period from on or

about January 22 to on or about November 11, 1940; and charging that portions of the articles were misbranded and that the remainder were adulterated and misbranded.

Analyses of samples of the Sterile Uteroids showed that they consisted essentially of ichthammol, menthol, an iodine compound (a trace of an iodine compound in one lot), and extracts of plant drugs, incorporated in wool wax (lanum); and that they contained no alum and no zinc sulfate. They were alleged to be adulterated in that their strength differed from and their quality fell below that which they purported and were represented to possess. They were alleged to be misbranded (1) in that the statement on the carton label, "Powd. Alum 10%. Zinc. Sulph. 1%," was false and misleading since they contained no alum and no zinc sulfate; (2) in that the statement on the carton label, "Sterile Uteroids For Intra-Uterine Treatment * * * Endometritis," was false and misleading; and (3) for the four further reasons appearing in the first paragraph of this notice.

Analysis of a sample of Prevent-All showed that it consisted essentially of calomel (4.4 percent) and zinc oxide (9.3 percent) incorporated in wool wax (lanum). It was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported or was represented to possess. It was alleged to be misbranded (1) in that the statement on the outer carton label, "Lanum base 67% Calomel 33%," was false and misleading in view of its actual composition; (2) in that the following statements on the outer carton were false and misleading: "Prevent-All A * * * Combination to Prevent All Sexual Diseases in the Male. Gonorrhea, Chancres (Syphilis). * * * Prevent-All * * * Gonorrhea or Syphilis, * * * Will Prevent It. Destroys micro-organism and prevents incubation. * * * Endorsed and recommended by leading physicians"; and (3) for the three further reasons appearing in the first paragraph of this notice.

Analysis of a sample of Leucorrhea Special No. 9 showed that it contained quinine sulfate (0.64 percent), boric acid (19.95 percent), and thymol, incorporated in petrolatum. It was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported or was represented to possess. The repackaged portion of this article was alleged to be misbranded (1) in that the statement on the label, "Quinine Sulph. 2% Powd. Boracic Acid 10%," was false and misleading since it contained materially less quinine sulfate and materially more boric (boracic) acid than the amounts stated; (2) in that the statements on the label of the repackaged portion, "Leucorrhea Special" and "For the Local Treatment of Leucorrhea," were false and misleading; and (3) for the four further reasons appearing in the first paragraph of this notice.

Analysis of a sample of Gleet Specific showed that it contained a mercury compound, calculated as mercury oxycyanide (0.2 percent (1–500)), eucalyptus oil, and an extract of a plant drug incorporated in wool wax (lanum). It was alleged to be misbranded (1) in that the statement on the label, "Gleet Specific," was false and misleading; (2) in that its label failed to bear a statement of the proportion of mercury, derivative of, or preparation of mercury that it contained since the statement on the label, "Mercury Oxy-cyanide 1–1500," was not an accurate statement of the proportion of mercury or mercury derivative or preparation that it contained: and (3) for the five further reasons appearing in the first paragraph of this notice.

Analysis of a sample of Argosine showed that it contained a silver compound such as argyrol, an extract of a plant drug, and water. It was alleged to be misbranded for the five reasons appearing in the first paragraph of this notice.

Analysis of a sample of Prostatic Depletent showed that it contained glycerin (approximately 12 percent), Epsom salt (approximately 6 percent), and water, emulsified. It was alleged to be misbranded in that the following statements on the label, "Prostatic Depletent * * * Highly depletent and cleansing, with immediate relief of congestion of the rectal area. Used as a Primary treatment on Prostatic disorders (Nonoperative)," were false and misleading; and for the five further reasons appearing in the first paragraph of this notice.

Analysis of a sample of Picricine showed that it consisted essentially of picric acid and eucalyptus oil incorporated in wool wax (lanum). It was alleged to be misbranded for the four reasons appearing in the first paragraph of this notice.

Analysis of a sample of the Prostatic Absorbent showed that it consisted essentially of ichthammol, juniper oil, and extracts of plant drugs incorporated in

wool wax (lanum). It was alleged to be misbranded in that the statements on the label, "Prostatic Absorbent" and "Soothing and relieving Chronic conditions of the Prostate and Bladder neck," were false and misleading; and for the five further reasons appearing in the first paragraph of this notice.

Analysis of a sample of Aesculus Pile Cerate showed that it consisted essentially of ichthammol, tar oil, and extracts of plant drugs incorporated in petrolatum. It was alleged to be misbranded in that the designation "Pile Cerate" and the statement "Relieves Bleeding, Itching, Blind, Protruding, Ulcerated Piles," on the carton label were false and misleading; and for the four further reasons appearing in the first paragraph of this notice.

Between December 31, 1940, and January 29, 1941, default decrees were entered ordering that the products be destroyed.

437. Misbranding of Syn-O-Scope and Synex. U. S. v. 9 Packages of Syn-O-Scope and 8 Bottles of Synex. Default decrees of condemnation and destruction. (F. D. C. Nos. 3551, 3552. Sample Nos. 52531–E, 52532–E.)

Each package of the Syn-O-Scope consisted of a vaporizing apparatus and a small unlabeled vial of liquid. The vaporizing apparatus would have been dangerous to health when used according to directions, and the label also bore false and misleading therapeutic claims. The vial of liquid and the bottles of Synex also failed to comply with certain labeling requirements of the law.

On December 23 and on or about December 27, 1940, the United States attorney for the Eastern District of Washington filed libels against the above-named products at Spokane, Wash., alleging that the articles had been shipped on or about August 24, 1940, by Syn-O-Scope Laboratories from Los Angeles, Calif.; and charging that they were misbranded.

Analyses of samples of the liquid contained in each package of Syn-O-Scope and of Synex showed that they consisted essentially of alcohol (19.5 percent by volume), camphor, eucalyptus oil, and water.

The Syn-O-Scope was alleged to be misbranded: (1) In that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely, "Syn-O-Scope The Modern and Scientific Instrument for the Application Of Medicaments To Irritated And Congested Nasal Passages. Directions: Unscrew the cap where hose is attached to Syn-O-Scope. Allow 15 to 20 drops of medicant to flow into the sponge within the barrel. Replace cap. Then, merely place the tip in the nostril, holding it in position by the hand. Grasp the mouthpiece between the lips and blow. Use the amount of pressure suitable to your own case, but not too hard at first. The harder you blow, the deeper the medicated vapor reaches into the nasal cavities. Each day of active use add 3 to 5 drops of medicament to the sponge." (2) In that the following statements, (carton) "Syn-O-Scope The Modern Treatment For Nasal Irritations And Congestions," and (circular) "Syn-O-Scope The Modern And Scientific Instrument For The Application of Medicaments To Irritated And Congested Nasal Passages," were false and misleading since they represented that it was efficacious for the purposes recommended; whereas it was not efficacious for such purposes. (3) In that the carton and vial containing the liquid did not bear the common or usual names of the active ingredients, including the quantity of alcohol. (4) In that the vial containing the liquid failed to bear a label containing the name and address of the manufacturer, packer, or distributor. (5) In that the carton and vial containing the liquid failed to bear a label containing a statement of the quantity of contents.

The Synex was alleged to be misbranded in that the label failed to bear (1) the common or usual names of the active ingredients; (2) the name and address of the manufacturer, packer, or distributor; and (3) an accurate statement of the quantity of contents.

On February 24, 1941, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

438. Misbranding of Wonder Salve. U. S. v. 13 Cans of Wonder Salve. Consent decree of condemnation and destruction. (F. D. C. No. 3164. Sample No. 19079–E.)

The labeling of this product bore false and misleading representations regarding its efficacy as indicated hereinafter. The article would be dangerous to health when used in the manner recommended and suggested in the labeling.

On October 10, 1940, the United States attorney for the Western District of Pennsylvania filed a libel against 13 cans of Wonder Salve at Pittsburgh, Pa.,

alleging that the article had been shipped in interstate commerce on or about December 21, 1939, by Brookgate Remedies Co. from Evansville, Ind.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of phenolic compounds, including 5.44 percent of carbolic acid, camphor, and turpentine in an ointment base.

The article was alleged to be misbranded in that the following statements on the label were false and misleading, since it would not be efficacious for the purposes for which it was so recommended: "For all cases of Inflammation or Infection. For * * * Mashed Members, Cinders or any other Foreign substances in the Eye." It was alleged to be misbranded further in that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely, "Apply salve freely to affected parts and bandage. For cinders or other foreign substance in eye, place salve on absorbent cotton and place same over closed eye and bandage."

The product was also alleged to be misbranded in violation of the Federal Caustic Poison Act, as reported in notice of judgment No. 103 published under that act.

On January 26, 1942, the shipper having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS FOR USE OR WARNING STATEMENTS[1]

439. Misbranding of Pine-Orum Compound. U. S. v. John C. Schaffer (Pine-Orum Chemical Co.). Plea of guilty. Fine, $50. (F. D. C. No. 4169. Sample No. 11224-E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the treatment of certain conditions and failed to comply with certain mandatory labeling requirements of the law as indicated hereinafter.

On September 13, 1941, the United States attorney for the Southern District of Mississippi filed an information against John C. Schaffer, trading as Pine-Orum Chemical Co., at New Augusta, Miss., alleging shipment on February 23, 1940, from the State of Mississippi into the State of Texas of a quantity of Schaffer's Pine-Orum Compound that was misbranded.

Analysis showed that the article was a medium heavy oil having a strong pine oil odor consisting essentially of a pine tar distillate containing sulfur or sulfur compounds and a small percentage of water.

It was alleged to be misbranded in that certain statements on the bottle label were false and misleading since they represented and suggested that the article was efficacious as a treatment and remedy for coughs, colds, flu, pneumonia, headache, indigestion, worms in humans and animals, cuts, burns, infections and blood poison, insect bites, tonsillitis, sore throat, toothache, pyorrhea, bruises, rheumatism, neuritis, sprains, stiff joints, old chronic sores, hemorrhoids, athlete's foot, itch, poison oak, dew poison and dandruff; that it would be efficacious to stop the flow of blood; that when used in the bath it would have medicinal properties, and it was efficacious for many animal ailments; whereas it was not efficacious for such purposes.

It was alleged to be misbranded further in that it was in package form and did not bear a label containing the name and place of business of the manufacturer, packer or distributor, placed thereon with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read under customary conditions of purchase, since the name and place of business of the manufacturer did not appear on the panel of the bottle label which was displayed under customary conditions of purchase. It was alleged to be misbranded further in that it was in package form and did not bear a label containing an accurate statement of the quantity of the contents in terms of measure; in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient; and in that its labeling did not bear adequate directions for use, since it was recommended for conditions requiring external application and the labeling bore no directions for external use.

On October 13, 1941, the defendant having entered a plea of guilty, the court imposed a fine of $50.

[1] See also Nos. 426, 427, 429–432, 434–436, 459, 460.

440. Misbranding of Cascarin Compound Tablets. U. S. v. 573 Bottles of S. C. Tablets Cascarin Compound Dr. Hinkle No. 3. Default decree of condemnation and destruction. (F. D. C. No. 3638. Sample No. 32634–E.)

On January 9, 1941, the United States attorney for the District of Arizona filed a libel against 573 bottles of the above-named product at Phoenix, Ariz., alleging that the article had been shipped by the Boyce Pharmacal Co. from Los Angeles, Calif., on or about July 10, 1940; and charging that it was misbranded.

Analysis of a sample showed that the tablets each contained alkaloidal material including strychnine sulfate (approximately 0.024 grain), podophyllin (approximately ⅛ grain), aloin (¼ grain), and an emodin-bearing drug such as cascara sagrada.

The article was alleged to be misbranded in that the label failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users, since it did not inform the purchaser that the tablets should not be taken when symptoms of appendicitis are present and that its use by children and elderly persons is particularly dangerous, and did not warn against frequent or continued use of the article when such use is capable of causing dependence upon laxatives to move the bowels. It was alleged to be misbranded further (1) in that the designation "Cascarin Compound," appearing on the label, was false and misleading since it suggested that the essential ingredient in the preparation was derived from some species of cascara when in fact its principal active ingredients were aloin, podophyllin, and strychnine; (2) in that the designation "Dr. Hinkle No. 3," appearing on the label, was false and misleading since it created the impression that the article had the essential composition described in the National Formulary for Hinkle's pills when in fact its composition differed therefrom, particularly in that it contained strychnine sulfate, which is not an ingredient of Hinkle's pills; and (3) in that the label failed to bear the common or usual name of each of its active ingredients since the coined word "Cascarin," appearing on the label in the list of ingredients, was not the common or usual name of any drug.

On February 10, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

441. Misbranding of Crawford's Sa-Lax and Crawford's Formula 53 with Vitamin E. U. S. v. 9 Bottles and 4 Bottles of Crawford's Formula 53 with Vitamin E and 50 Tins of Crawford's Sa-Lax. Default decree of condemnation and destruction. (F. D. C. Nos. 3556, 3558. Sample Nos. 32615–E, 32622–E.)

The label of Crawford's Sa-Lax failed to bear adequate directions and warning statements; and the labeling of both products bore false and misleading therapeutic claims.

On January 6, 1941, the United States attorney for the District of Arizona filed a libel against the above-named products at Tucson, Ariz., alleging that Crawford's Formula 53 had been transported on or about July 18, 1940, by Walter Bopp from Eagle Rock, Calif., and that Crawford's Sa-Lax had been transported on or about July 26, 1940, by Crawford Foods, Inc., from Los Angeles, Calif.; and charging that they were misbranded.

Analyses of samples of the articles showed that Crawford's Sa-Lax Tablets contained the laxative drugs rhubarb root and senna leaf together with Irish moss, okra, and leafy plant materials such as parsley; and that Crawford's Formula 53 Tablets contained plant materials, largely alfalfa (lucerne) leaf and stem tissues, with smaller proportions of other plant materials including tomato seed, anise, fennel, Cayenne pepper (capsicum), celery seed, a leafy material such as parsley, and yeast.

Crawford's Sa-Lax was alleged to be misbranded (1) in that its package failed to bear adequate directions for use since the directions on the bottle label, "The dosage of Crawford's Sa-Lax must be determined by the severity of the case. The adult dosage suggested is two tablets upon retiring, to be increased to one tablet four times per day, with meals and upon retiring in the more severe cases. Children in proportion to age," were not suitable nor appropriate directions for the use of a laxative preparation of the composition of this one and therefore were not adequate; and (2) in that its labeling failed to bear adequate warnings against use in certain pathological conditions or methods or duration of administration in such manner and form as are necessary for the protection of users since its label failed to inform the purchaser that it would be dangerous if

consumed by a person suffering from appendicitis, and it failed to inform purchasers that frequent or continued use might result in dependence on laxatives. It was alleged to be misbranded further in that the following statements appearing on the bottle label were false and misleading with respect to the active laxative ingredients and with respect to the effects it would produce upon the consumer: "The active principles in this formula are parsley and asparagus. Parsley and asparagus appear to maintain a higher alkalinity through the intestine and into the colon than do other vegetables of higher initial alkaline content. Any decrease in the acidity of the waters absorbed from the colon and carried by the portal circulation to the liver evidently minimizes the alkaline demand upon the liver to bind such acid. Any conservation of the alkaline demand upon the liver facilitates the liver's fabrication and secretion of a more alkaline or normal bile, which will result in more complete digestion, minimized fermentation and lowered putrefaction within the colon. Neither parsley nor asparagus produces any laxative effect. Okra is included in this formula for the excellent property of its vegetable mucin. Irish moss is included for its property of absorbing and holding the water and thus effecting a higher degree of softness of the colonic residues."

Crawford's Formula 53 with Vitamin E was alleged to be misbranded in that representations and suggestions in the labeling that it would be efficacious in building blood, supplying the necessary vitamins and minerals to the blood stream for restoring the normal functions of the body mechanism; that it would be efficacious in maintaining the tone of the sacral nervous system, in helping to maintain the sex power, in helping to maintain high vitality through building up the entire glandular system; that it would aid in building up the skin tissuses and that it would endow the blood with such properties as would give the consumer long life, health, energy, and vitality; that it would be efficacious in case of pale and livid complexion, dry skin, bluish, white, or gray gums, transparent and waxy ears, habitually cold feet, continually clammy hands, bluish and lusterless fingernails, dull-looking hair, decaying teeth, pyorrhea, drawn face, coarse and yellow skin, or foul breath; that it would be efficacious when physical exertion causes shortness of breath, palpitation of the heart, or rapid or weak pulse; that it would be efficacious when mental and emotional fatigue are present, when one feels fear or apprehension, loses faith in oneself, or is nervous, listless, unstable, and despondent; that because of its ability to form red cells in the blood and increase the amount of hemoglobin in the red cells it would be efficacious in anemia accompanied by lack of energy, languor, fatigue, and lack of persistence; that it would be efficacious in nourishing and rebuilding the tissues, regardless of the nature of the ailment; that it would be efficacious in the treatment of arthritis, rheumatism, heart disease, degenerative diseases, and bladder, liver, and kidney troubles; and that it would develop a strong friendly overpowering personality which would command the respect and love of everyone and allow the user to be more useful to himself, friends, and children; that it would be efficacious when one is grouchy, tired, feeling miserable, cannot sleep, and is suffering from pains all over the body; that it would rejuvenate the body; that it would be efficacious for the treatment of tumors and growths such as cancer by dissolving the tumor and growth; and that its use would enable the user to regain health and vigor, were false and misleading since it would not be efficacious for such purposes.

The libel alleged that Crawford's Formula 53 was also misbranded under the food provisions of the law as reported in F. N. J. No. 2819.

On February 21, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

442. Misbranding of Germania Herb Tea. U. S. v. 1,250 Packages of No. 14 Germania Herb Tea. Default decree of condemnation and destruction. (F. D. C. Nos. 3816, 3817. Sample Nos. 40253-E, 40254-E.)

The label of this product not only failed to bear adequate directions for use; but it contained false and misleading statements regarding its efficacy as an aid in weight reduction and in the treatment of various diseases, and it failed to bear the common or usual name of each of the active ingredients.

On February 14, 1941, the United States attorney for the Eastern District of Pennsylvania filed a libel against 600 sample packages and 650 retail packages of Germania Herb Tea at Philadelphia, Pa., alleging that it had been shipped by the Germania Tea Co. from Minneapolis, Minn., and by Consolidated Drug Trade

Products, Inc., from Chicago, Ill., on or about January 15 and 22, 1941; and charging that it was misbranded.

Examination of a sample of the article showed that it consisted of senna leaves (approximately 40 percent) with smaller proportions of other leaves, buds, seeds, stems and flowers including arnica flowers, uva ursi leaves, aniseed, and Cyanus flowers.

The article was alleged to be misbranded: (1) In that its labeling failed to bear adequate directions for use, since directions contained in an accompanying booklet entitled "Food," that users drink Germania Herb Tea with meals as needed for a few weeks, were not appropriate for an article of its composition and therefore were not adequate. (2) In that statements in the aforesaid booklet and in a leaflet entitled "Insist on Genuine No. 14 Germania Herb Tea," representing that its use would give the consumer a normal, healthy, and beautiful figure; that it would be effective for the relief of many body aches and pains; that it would give regular elimination for a healthy stomach; that it would be efficacious in the treatment of stomach-heartburns, sour stomach, belching, vomiting, biliousness, dizzy spells, gas in the stomach and bowels, loss of appetite and restless nights; that by its use one could avoid constipation; that it would be efficacious in the treatment of rheumatic aches and pains; that its use would give the consumer a clear complexion, would stimulate functional kidney action, would aid in weight reduction, and would help promote elimination of wastes through the kidneys and gastro-intestinal organs, were false and misleading since it would not be efficacious for such purposes. (3) In that its label failed to bear the common or usual name of each active ingredient, since the statement on the label, "No. 14 Germania Herb Tea is Composed of T. V. Senna Leaves, Black Tea, Acacia Flowers, Cyani Flowers, Pansy Herb, Uva Ursi Leaves, Arnica Flowers, Blackberry Leaves, Raspberry Leaves, Sweet Violet Leaves, Horse Tail, Elder Flowers, Woodruff Herb, Fennel Seed, Aniseeds and Camomile Flowers," did not indicate which of the plant materials mentioned are physiologically or therapeutically active.

On March 8, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

443. Misbranding of Gid. U. S. v. 105 Packages and 2,900 Envelopes (free samples) of Gid Granules No. 1 and 169 Packages of Gid Granules No. 2. Default decree of condemnation and destruction. (F. D. C. No. 4854. Sample Nos. 36782–E, 36783–E.)

The labeling of the free samples of this product failed to bear adequate directions for use, the common or usual name of each of the active ingredients, the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of contents. The labeling of the regular packages bore false and misleading statements regarding its ingredients and its therapeutic properties.

On June 2, 1941, the United States attorney for the District of Massachusetts filed a libel against the above-named products at Boston, Mass., alleging that they had been shipped by Eberly-Williams Manufacturing Co. from Chicago, Ill., on or about April 9 and 17, 1941; and charging that they were misbranded.

Analyses of samples of the articles showed that Gid Granules No. 1 consisted essentially of the mucilaginous part of psyllium seed, karaya gum, sodium bicarbonate in proportions varying from 1.2 percent to 8.2 percent, calcium carbonate in proportions varying from 0.79 percent to 9.2 percent, a phosphate, a sulfate, and sugar; and that Gid Granules No. 2 consisted essentially of the mucilaginous part of psyllium seed, karaya gum, yeast, and sugar.

The free samples of Gid Granules No. 1 were alleged to be misbranded for the reasons stated above. Gid Granules No. 1 were alleged to be misbranded in that the statement, (carton) "Calcium Carbonate . . . 9% Sodium Bicarbonate . . . 9%," was false and misleading since it did not contain the declared proportions of calcium carbonate and sodium bicarbonate; and in that the statement, (carton) "are scientifically prepared to be of effective value in the treatment of minor irritations and inflammations of the stomach and upper intestines, a protective demulcent * * * Dosage four grams (one teaspoonful) three or four times daily," was false and misleading since the article was not an appropriate and effective medicament for the conditions mentioned and it did not possess the properties claimed when used as stated. Gid Granules No. 2 were alleged to be misbranded in that the statement, (carton) "are scientifically prepared to be of effective value in the treatment of minor irritations and inflammations of the lower intestine and colon, and in spastic * * *

constipation," were false and misleading since the article did not constitute an adequate treatment for the conditions mentioned. Both articles were alleged to be misbranded in that statements in an accompanying circular entitled "A Message of Hope," representing that it would be efficacious for relief from the distressing symptoms in many cases of stomach troubles, indigestion, sore stomach, bad breath, gnawing pains, gas pains, dyspepsia, intestinal disorders, biliousness, headache, sleeplessness, intestinal stasis, auto-intoxication, colitis, colonic irritation, liver and gall deficiencies not due to infection; that Gid means gastro-intestinal demulcence; that it would be efficacious as an aid for gastro-intestinal lacerations, ulcers, lesions, stasis, constipation, and toxemia; that Gid would coat offensive particles of the intestinal contents and every square inch of stomach-intestinal wall with its protective demulcence; that it would tend to correct diarrhea, tuberculosis, and cancer of the gastric tract; that Gid No. 1 was especially adapted to neutralize the excess acidity of the jejunum and upper intestine; and that Gid No. 2 was particularly fitted for use in troubles located in the lower intestines, cecum, ascending and transverse colon, sigmoid, and rectum, were false and misleading since it would not be efficacious for such purposes.

On July 8, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

444. Misbranding of Gly-Cas. U. S. v. 258 Cartons of Gly-Cas. Default decree of condemnation. Product destroyed. (F. D. C. No. 3647. Sample No. 8978–E.)

The labeling of this product, in addition to failure to bear the warning statement required in the labeling of laxative preparations, also bore false and misleading therapeutic and other claims, and it failed to indicate which of the ingredients was the active ingredient.

On January 17, 1941, the United States attorney for the District of South Dakota filed a libel against 258 cartons of Gly-Cas at Sioux Falls, S. Dak., alleging that the article had been shipped on or about November 25, 1940, by the Gly-Cas Medicine Co. from Muncie, Ind.; and charging that it was misbranded.

Analysis of a sample of the article, which was in capsule form, showed that each capsule contained approximately 4.3 grains of drugs from plant sources including aloe and a small proportion of glycerin.

The article was alleged to be misbranded in that the labeling failed to bear such adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users in that it did not inform the purchaser that continual or frequent use of the article might result in dependence upon laxatives to move the bowels. It was alleged to be misbranded further in that representations in the labeling that its use would put one "in Step with Health"; that it would be efficacious in the treatment of those who suffer with muscular aches and pains, poor digestion, soured, gassy feeling after eating, bloated stomach; night risings, backaches; dizzy spells, headaches, nervousness or poor sleep kindred to faulty bowel elimination, frequent bladder action, loss of pep and energy, inability to work, and restlessness; and that it had proved effective in many cases where other medicines tried before had failed to give satisfactory results, were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further in that the statement in the circular "Contains No * * * Harmful Drugs," was false and misleading since the article was capable of causing harm; in that the statement that the article was a product of over 25 years of practical experience of a well-known pharmacist was false and misleading since it was essentially a preparation of aloe, a drug whose properties had been known for centuries; and in that its label failed to bear the common or usual name of the active ingredient in that the statement on the carton, "Compound of Cinnamon, Aloe, Glycerin and Licorice," did not indicate what was really its active ingredient.

On February 17, 1941, no claimant having appeared, judgment of condemnation was entered; and on February 25, 1941, the product was destroyed.

445. Misbranding of Grover Graham Remedy (and Graham's Pills). U. S. v. 33 12-Fluid-Ounce Packages and 42 6-Fluid-Ounce Packages of Grover Graham Remedy. Default decree of condemnation and destruction. (F. D. C. No. 3915. Sample No. 34897–E.)

Each package of this product contained an envelope labeled "Graham's Pills." The labeling of Grover Graham Remedy and Graham's Pills failed to bear

adequate directions for use—in the former case because no limitation was put on the amount of bromide that might be administered daily, and in the latter case because the directions provided for excessive dosage. The labeling of both products also failed to bear adequate warning statements, but did bear false and misleading therapeutic claims.

On March 4, 1941, the United States attorney for the District of New Jersey filed a libel against the above-named products at Newark, N. J., alleging that the articles had been shipped by Kells Co. from Newburgh, N. Y., on or about November 29, 1940, and January 9 and 25, 1941; and charging that they were misbranded.

Analyses of samples of the articles showed that Grover Graham Remedy consisted essentially of magnesia, sodium bicarbonate, sodium bromide, alcohol, water, and small amounts of chloroform, ginger, and peppermint oil; and that Graham's Pills consisted essentially of laxative plant drugs.

Both products were alleged to be misbranded: (1) In that they failed to bear adequate directions for use as stated above. (2) In that the labeling failed to bear such adequate warnings against use in those pathological conditions where their use might be dangerous to health, or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users. (3) In that statements in the labeling which represented that Grover Graham Remedy would give instant relief for severe attacks of indigestion and all stomach ills, and that it would be efficacious as a dyspepsia remedy and for gastritis and bloating; and that Graham's Pills were efficacious in the treatment of biliousness, were false and misleading since they would not be efficacious for such purposes. Graham's Pills were alleged to be misbranded further in that the label did not bear an accurate statement of the quantity of contents.

On April 18, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

446. Adulteration and misbranding of Heads-Up Headache Powders and misbranding of Digesto-Pep and Coldlax. U. S. v. 126 Packages of Heads-Up, 70 Packages of Digesto-Pep, and 31 Bottles of Coldlax. Default decree of condemnation and destruction. (F. D. C. No. 4026. Sample Nos. 20666–E, 20667–E, 20668–E.)

The labeling of the headache powders and the Coldlax failed to bear such adequate warnings as are necessary for the protection of users and failed to bear adequate directions and the common or usual names of the active ingredients. The "Heads-Up" contained acetylsalicylic acid, sodium bromide, and phenolphthalein in excess of the amount declared. The labels of all products bore false and misleading representations regarding their curative and therapeutic efficacy.

On March 25, 1941, the United States attorney for the Northern District of Georgia filed a libel against the above-described drugs at Atlanta, Ga., alleging that the articles had been shipped in interstate commerce on or about December 10, 1940, by Smith Bros. Drug Co. from Greensboro, N. C.; and charging that they were misbranded and that the Heads-Up Headache Powders were also adulterated.

Analyses showed that the average Heads-Up headache powder contained 4.68 grains of aspirin, 6.62 grains of sodium bromide, and 0.57 grain of phenolphthalein; that the Digesto-Pep contained alkaline compounds, including a bismuth compound and diastase; and that the Coldlax consisted essentially of water, alcohol, sodium salicylate, a laxative plant drug, menthol, camphor, and traces of alkaloids.

The Headache Powders were alleged to be adulterated in that their strength differed from that which they purported or were represented to possess, since each powder contained materially more acetylsalicylic acid, sodium bromide, and phenolphthalein than the amounts stated on the label. They were alleged to be misbranded in that the statement on the label, "Each Powder Contains: Acidum Acetylsalicylic * * * 4 Gr. * * * Sodium Bromide * * * 6 Gr. Phenolphthalein * * * ¼ Gr.," was false and misleading since it was incorrect. They were alleged to be misbranded further in that the statements on the label, "Brace Up! with Heads-Up," "With Heads-Up You'll Brace Up!," and "'Go Smiling Thru' As Thousands Do," were false and misleading as the article could not be depended upon to brace one up or to enable one to "go smiling through" when suffering from the various disease conditions mentioned on the label. They were alleged to be misbranded further in that the statements, "Take With Confidence," "Heads-Up is different * * * safe * * * faster," and

"Heads-Up contains no acetanilid, harmful or habit forming drugs," were false and misleading, since they might cause potentially harmful effects, they were not essentially different from or safer than various other preparations on the market, were not safe under all conditions, and contained potentially harmful and habit-forming drugs. They were alleged to be misbranded further in that the label failed to bear the common or usual name of each of the active ingredients since acidum acetylsalicylic is not the common name for aspirin. They were alleged to be misbranded further in that the labeling failed to bear adequate directions for use, since the direction "Take one powder every two or three hours as needed" was not adequate for an article of the composition of Heads-Up Headache Powders.

The Digesto-Pep was alleged to be misbranded in that the designations "Digesto-Pep," "Aids Digestion," and "Intended for use in correcting conditions associated with * * * sluggish digestion," appearing on the label, were false and misleading, since it was not a digestant of the various constituents of food, could not be depended upon to produce "pep" and aid digestion and correct sluggish digestion. It was alleged to be misbranded further in that the statements on the label "'Keep in step with Digesto-Pep'" and "'Go smiling thru' as thousands do" were false and misleading, since the article could not be depended upon to fulfill the promises of benefit expressed and implied by this language.

The Coldlax was alleged to be misbranded in that the designation "Coldlax" and the statement "For the relief of colds," appearing on the carton and bottle label, and the statement "For Colds," appearing in the directions, were false and misleading, since it did not constitute an adequate treatment for colds; and in that the unmodified statement "For Coughs" in the directions was false and misleading, since the article did not constitute an adequate treatment for coughs from all causes. It was alleged to be misbranded further in that the statement in the directions, "Coldlax contains no habit forming drugs" was false and misleading, since it contained aromatic fluidextract of cascara sagrada by reason of which frequent or continued use of the article might cause dependence upon laxatives to move the bowels; in that the label failed to bear the common or usual name of each active ingredient, since "Alkaloids" is not the common or usual name of any constituent of the preparation, and the names of other constituents were given in abbreviated form; and in that its labeling failed to bear adequate directions for use, since the directions given did not limit the period of time over which the article might appropriately be consumed.

The Heads-Up and Coldlax were alleged to be misbranded further in that their labeling failed to bear adequate warnings against use in those pathological conditions and by children where use might be dangerous to health and against unsafe dosage and duration of administration in such manner and form as are necessary for the protection of users since the labeling failed to bear a warning that the articles should not be used in cases of nausea, vomiting, abdominal pain, and other symptoms of appendicitis and did not warn that frequent or continued use of the articles might result in dependence upon laxatives to move the bowels.

On April 21, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

447. Misbranding of Laxrid. U. S. v. 72 10-Ounce Packages and 33 4-Ounce Packages of Lawrence Mack's Laxrid. Default decree of condemnation and destruction. (F. D. C. No. 3825. Sample No. 52201-E.)

The labeling of this product failed to bear adequate directions for use, and it also contained false statements regarding its ingredients, its efficacy as a weight reducer, and its therapeutic qualities.

On February 20, 1941, the United States attorney for the District of Oregon filed a libel against the above-named product at Portland, Oreg., alleging that it had been shipped by Lawrence Mack, Inc., from Detroit, Mich., on or about January 6, 1941; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of Epsom salt, Glauber's salt, sodium bicarbonate, tartaric acid, citric acid, and small quantities of sodium phosphate, potassium and sodium chlorides, saccharin, and peppermint oil.

The article was alleged to be misbranded: (1) In that its label failed to bear adequate directions for use since those given were not suitable for a laxative. (2) In that the following statements in the label (carton and circular) "Report of Laboratory Test of Lawrence Mack's Laxrid. 'We have tested a sample of Lawrence Mack's Laxrid and find that it is entirely free from any of the poisonous

and harmful substances listed below: Alkaloids...None Narcotics...None Phenolic Substances...None Alcohols...None Veronal, Barbital, and similar compounds...None Metallic Poisons...None (Salts of lead, arsenic, antimony, mercury, tin, bismuth and barium) Di-nitrophenol...None Plant Tissues...None (Pokeweed, bladder wrack, etc.) Thyroid Extract...None,'" were false and misleading since they gave the impression that the article contained no deleterious substances. (3) In that statements in the booklet entitled "How I Reduced," representing that its use would "Do Away With Excess Weight," relieve constipation, that reduction of weight gained by its use usually was permanent; that it would remove heaviness in body, take away that bloated, sluggish feeling; would enable the user to get up full of vim, vigor, and vitality; and that it would relieve gas and acids, were false and misleading since it would not be efficacious for such purposes.

On April 17, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

448. Misbranding of mineral oil. U. S. v. 1,122 Bottles of Mineral Oil. Consent decree of condemnation. Product ordered released under bond for relabeling. (F. D. C. No. 4859. Sample Nos. 56418–E, 56419–E.)

This product was light mineral oil and not heavy mineral oil as suggested by its labeling. Moreover, its labeling failed to bear such warnings as are necessary for the protection of users.

On June 2, 1941, the United States attorney for the Eastern District of New York filed a libel against 1,122 bottles of mineral oil at Brooklyn, N. Y., alleging that the article had been shipped in interstate commerce within the period from on or about March 9 to on or about May 3, 1940, by Purex Products, Inc., from Boston, Mass.; and charging that it was misbranded. The article was labeled in part: "PuRex Russian Mineral Oil Light."

The article was alleged to be misbranded in that the designation "Russian Mineral Oil" (in comparatively large type) and the word "Light" (in comparatively small type) borne on the label were misleading, since the term "Russian Mineral Oil" is associated in the minds of purchasers with an oil having a kinematic viscosity, which is substantially higher than that of the article.

It was alleged to be misbranded further in that its labeling failed to bear adequate warnings against unsafe methods of administration in such manner and form as are necessary for the protection of users, since the labeling carried no warning against its administration directly before or after meals.

On June 24, 1941, Purex Products, Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be relabeled to comply with the law.

449. Adulteration and misbranding of solution of citrate of magnesia. U. S. v. 137 Bottles of Solution of Citrate of Magnesia. Default decree of condemnation and destruction. (F. D. C. No. 3402. Sample No. 20499–E.)

This product contained less magnesium citrate and less citric acid than the amounts required by the United States Pharmacopoeia. Its labeling also failed to bear a statement of the quantity of the contents or a warning against its use in those pathological conditions where its use might be dangerous to health.

On November 23, 1940, the United States attorney for the Southern District of Georgia filed a libel against 137 bottles of the above-named product at Augusta, Ga., alleging that it had been shipped in interstate commerce on or about September 10, 1940, by the McMillan Drug Co. from Columbia, S. C.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be or was represented as a drug, the name of which is recognized in the United States Pharmacopoeia, and its strength differed from the standard set forth therein.

It was alleged to be misbranded in that it was a drug in package form and the label failed to bear an accurate statement of the quantity of contents; and in that the labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health as might be necessary for the protection of users.

On January 1, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

450. Misbranding of National Peerless Remedy. U. S. v. 23 Bottles of National Peerless Remedy. Default decree of condemnation and destruction. (F. D. C. No. 3512. Sample No. 50103–E.)

The label of this product not only failed to bear adequate directions and warning statements but also the common or usual name of each of the active ingredients, which included extracts of plant drugs including aloe.

On December 13, 1940, the United States attorney for the Middle District of Pennsylvania filed a libel against 23 bottles of National Peerless Remedy at Chambersburg, Pa., alleging that the article had been shipped by the National Pharmaceutical Manufacturing Co. from Baltimore, Md., on or about June 20, 1940; and charging that it was misbranded.

It was alleged to be misbranded (1) in that the label failed to bear adequate directions for use; (2) in that the label failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users; and (3) in that the label failed to bear the common or usual name of each active ingredient.

On June 16, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

451. Misbranding of O'D Easylax. U. S. v. 2 Gross Packages of O'D Easylax. Default decree of condemnation and destruction. (F. D. C. No. 3650. Sample No. 50056–E.)

In addition to failure to bear adequate warnings, the label of this product bore false and misleading therapeutic claims. It also failed to bear the required ingredient statement with the quantity or proportion of strychnine present; a statement of the quantity of contents; and the complete address of the manufacturer, packer, or distributor. Furthermore, the carton container was much taller than was necessary to hold its contents.

On January 9, 1941, the United States attorney for the District of Columbia filed a libel against 2 gross packages of O'D Easylax at Washington, D. C., alleging that the article was being offered for sale in the District of Columbia at Washington Wholesale Drug Exchange, Washington, D. C.; and charging that it was misbranded. It was labeled in part: "O'D Easylax * * * Liberty Drug Co. Washington, D. C."

Analysis of a sample of the article showed that it consisted essentially of phenolphthalein, aloin, strychnine, talc, and calcium carbonate together with a green coloring material.

It was alleged to be misbranded (1) in that labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application; (2) in that the following statements appearing on the label were false and misleading since it was not efficacious for the purposes recommended: (Carton) "They work naturally and form no habit * * * A Home Remedy for Indigestion Torpid Liver Chronic Constipation," and (bottle label) "They work naturally and form no habit. For Indigestion"; (3) in that the label did not bear the common or usual names of the active ingredients and a statement of the quantity or proportion of strychnine that it contained; (4) in that the carton and bottle label failed to bear the address of the manufacturer, packer, or distributor; (5) in that the bottle label failed to bear a statement of the quantity of contents; and (6) in that the container was so made, formed, or filled as to be misleading.

On February 4, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

452. Misbranding of Prunlax. U. S. v. 236 Bottles of Prunlax. Default decree of condemnation and destruction. (F. D. C. No. 3960. Sample No. 57020–E.)

On March 12, 1941, the United States attorney for the Eastern District of Missouri filed a libel against 31 12-fluid-ounce, 131 5-fluid-ounce, and 74 sample-sized packages of Prunlax at St. Louis, Mo., alleging that the article had been shipped by Adams Laboratories, Inc., from St. Louis, Mo., to Cleveland, Miss., on or about October 11, 1940, and that it had been shipped from Cleveland to St. Louis on or about October 14, 1940; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of extracts of plant materials including laxative plant drugs, sugar, glycerin, flavoring materials, and water, preserved with salicylic acid.

The article was alleged to be misbranded: (1) In that the directions (sample package) "Children One-quarter to one teaspoonful. Adults—One to two teaspoonfuls," and (remainder of product, bottle label) "Adjust dose to individual needs. And, taper off as action becomes normal. Children: According to age, one-quarter to one teaspoonful as needed. Adults: One to two teaspoonfuls night and morning until regulated," and (carton) "Dose: Children, 3 to 5 years, one-quarter teaspoonful; 5 to 9 years, one-half teaspoonful; 9 to 15, one teaspoonful. Adults, one to two teaspoonfuls night and morning until bowels act well," were not appropriate and were otherwise not adequate. (2) In that its labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users, since the labeling did not inform the purchaser that its use was contraindicated in cases of appendicitis and that frequent or continued use might result in dependence upon laxatives to move the bowels. (3) In that the name "Prunlax" was false and misleading since the active laxative ingredients in the preparation were not derived from prunes; in that the statement on the bottle labels, "To further promote its helpful harmony with health processes of the body, no phenolphthalein, alcohol, or other disturbing drug is used in Prunlax," was false and misleading since Prunlax cannot be depended upon to act in helpful harmony with health processes of the body, and the statement would tend to create the impression that the article contained no potentially harmful or deleterious ingredients, when such was not the case; and in that representations in the labeling that it was a safe laxative which would correct constipation without habit formation and without the use of irritating drugs; that it was especially helpful in cases of biliousness, sour stomach, colic due to gas, and diarrhea due to improper diet; and that it would prevent the user from having dizzy spells, were false and misleading since it would not be safe under all conditions and would not be efficacious for the disease conditions mentioned. (4) In that the sample-sized package failed to bear a label containing the common or usual name of each of its active ingredients. (5) In that the sample-sized package failed to bear a label containing a statement of the quantity of contents.

On May 3, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

453. Misbranding of Rogers Headache Soda. U. S. v. 95 Dozen and 3½ Dozen Packages of Rogers Headache Soda. Default decree of condemnation and destruction. (F. D. C. No. 4000. Sample Nos. 39686–E, 39700–E.)

This product contained acetanilid and its label did not bear adequate directions for use and such adequate warnings as are necessary for the protection of users. It contained not more than 1.9 grains of acetanilid per powder, whereas it was labeled as containing 2½ grains of acetanilid per powder. Its principal ingredient was not soda as suggested by its name.

On March 20, 1941, the United States attorney for the Eastern District of Illinois filed a libel against 95 dozen 10-cent packages and 3½ dozen 25-cent packages of Rogers Headache Soda at Cairo, Ill., alleging that the article had been shipped in interstate commerce on or about November 7, 1940, and February 4, 1941, by the Rogers Drug Co. from Memphis, Tenn.; and charging that it was misbranded.

The article was alleged to be misbranded in that the statements on the label, "Headache Soda—Each Powder Contains 2½ grs. Acetanilid," were false and misleading since they were incorrect. It was alleged to be misbranded further in that the label did not bear a statement of the quantity or proportion of acetanilid contained in the article; and in that the label did not bear adequate directions for use and adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users.

On April 26, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

454. Misbranding of Rux compounds and Williams formulas. U. S. v. Certain Quantities of Rux Compound Regular, Rux Compound Strengthened, Williams Formula Regular, and Williams Formula Strengthened. Default decree of condemnation and destruction. (F. D. C. No. 3390. Sample Nos. 24139-E to 24143-E, incl.)

The label of the Williams formulas failed to bear adequate directions and warning statements, and that of all four products bore false and misleading therapeutic claims.

On November 18, 1940, the United States attorney for the Middle District of Pennsylvania filed a libel against 29 bottles of Rux Compound Regular; 191 8-fluid-ounce bottles, 16 3-fluid-ounce bottles, and 2 quart bottles of Rux Compound Strenthened; 27 bottles of Williams Formula Regular; and 195 8-fluid-ounce bottles, 20 3-fluid-ounce bottles, and 2 quart bottles of Williams Formula Strengthened at Sayre, Pa., alleging that the articles had been shipped on or about July 26, 1940 by the Williams S. L. K. Laboratories from Milwaukee, Wis.; and charging that they were misbranded.

Analyses of samples showed that Rux Compound Regular consisted essentially of sodium, potassium, and strontium salts of salicylic, benzoic, and acetic acids, extracts of plant drugs including quassia, saccharin, and water, the total amount of salicylic acid represented being 21.1 grains per fluid ounce; Rux Compound Strengthened consisted essentially of the same ingredients, the total amount of salicylic acid represented being 32.8 grains per fluid ounce; Williams Formula Regular consisted essentially of Rochelle salt (21.5 grains per fluid ounce), methenamine (5.2 grains per fluid ounce), iron and ammonium citrate (2.4 grains per fluid ounce), extracts of plant drugs including a laxative drug, nux vomica, and Cayenne pepper, alcohol (3 percent), and water; and Williams Formula Strengthened consisted essentially of Rochelle salt (40.2 grains per fluid ounce), methenamine (9.3 grains per fluid ounce), iron and ammonium citrate (3.8 grains per fluid ounce), extracts of plant drugs including a laxative drug, nux vomica, and Cayenne pepper, alcohol (2.3 percent), and water.

Williams Formula Regular and Williams Formula Strengthened were alleged to be misbranded in that the labeling did not bear adequate directions for use since the following directions were not suitable and appropriate for articles of their composition and therefore were not adequate: (Bottle and carton containing Williams Formula Regular and 8-fluid-ounce bottle and carton containing Williams Formula Strengthened) "Adults—Tablespoonful before meals and at bedtime with a glass of water with each dose. Reduce dose if too active"; (circular accompanying 8-fluid-ounce bottle of Williams Formula Strengthened) "Important Directions Williams Formula is generally taken right before meals and at bedtime, making four doses a day to start. * * * Follow carefully directions for dosage on label. If desired, 2 teaspoonsful may be taken each dose for a few days. Reduce dose if too active. * * * After taking a course of Williams Formula many people prefer to keep a bottle on hand to be taken as needed. Some find it advisable to take the medicine a week or ten days, then skip a week or two, resuming the dosage when they feel the need of it. Your own experience should soon guide as to how to take Williams Formula to obtain the most good from it. * * * Directions For Combination Use When using Rux and Williams Formula together, in indicated conditions, follow these directions: Take 2 teaspoonsful of Rux every 3 hours for the first 3 days, and Williams Formula before meals and at bedtime. After 3 days, take 1 teaspoonful of Rux after meals and at bedtime, using Williams Formula morning and night only. In this way one bottle of Williams Formula lasts as long as two bottles of Rux." Williams formulas were alleged to be misbranded further in that the labeling failed to bear adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users, since it did not inform the purchaser that frequent or continued use of the article might result in dependence upon laxatives to move the bowels. They were alleged to be misbranded still further in that representations in the labeling that Williams Formula Regular would provide iron for the blood and an alkalizer for excess stomach acid; that it would be efficacious in the treatment of constipation, sick headaches, dizzy attacks, nausea, poor appetite, gas pains, bloat, tired-out, run-down, "half-alive" feeling; that it had helped bring users to a greater enjoyment of living; that it would relieve suffering and make life happier; that it would give gentle laxing action; that it would serve as a tonic to help whip the user out of depressing mental laziness and give him increased pep and vitality; that it would

alkalize urine flow to relieve acid kidney pains, and that it would serve as a diuretic for kidneys; that it would cure pimples, relieve choking spells, and tone up the intestinal muscles; and that Williams Formula Strengthened was an iron source, were false and misleading since the drugs were not efficacious for such purposes.

Rux Compound Regular and Rux Compound Strengthened were alleged to be misbranded in that representations in the labeling that they were efficacious for pronounced pain and for relief of muscular pain and congestion, were false and misleading since they would not be efficacious for such purposes.

On June 30, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

Nos. 455 to 457 report the seizure and disposition of intra-cervical or intra-uterine types of metal or rubber-covered stem pessaries which were potentially dangerous.

455. Misbranding of pessaries. U. S. v. 8 Gold Pessaries. Default decree of condemnation and destruction. (F. D. C. No. 3004. Sample No. 34352–E.)

On September 19, 1940, the United States attorney for the Eastern District of New York filed a libel against 8 gold pessaries at Brooklyn, N. Y., alleging that the article had been shipped on or about November 19, 1938, March 14, 1939, and July 23, 1940, by American Platinum Works from Newark, N. J.; and charging that its was misbranded in that its labeling failed to bear adequate directions for use.

On November 14, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

456. Misbranding of pessaries. U. S. v. 1 Large, 2 Small, and 6 Medium Gold Pessaries. Default decree of condemnation. Product ordered delivered to United States Mint. (F. D. C. No. 3309. Sample No. 35296–E.)

On or about November 2, 1940, the United States attorney for the Northern District of Texas filed a libel against 9 gold pessaries at Fort Worth, Tex., alleging that the article had been shipped on or about September 10, 1940, by the Kny-Scheerer Corporation from Long Island City, N. Y.; and charging that it was misbranded. It was labeled in part: "Perfection 1/10 14 Kt. Gold Pessary."

The article was alleged to be misbranded (1) in that its labeling did not bear adequate directions for use; and (2) in that its labeling did not bear adequate warnings against use in those pathological conditions where its use might be dangerous to health or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for protection of users.

On February 26, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to the Director of the Mint for reclamation, for the use of the United States, of its gold content.

457. Misbranding of pessaries. U. S. v. 125 Gold Pessaries. Consent decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 3095. Sample Nos. 30915–E to 30920–E, incl.)

On October 15, 1940, the United States attorney for the Northern District of Illinois filed a libel against 125 pessaries at Chicago, Ill., alleging that the article had been shipped by Nicholas Mandula from New York, N. Y., on or about August 28, 1940; and charging that it was misbranded. It was labeled in part: "Illinois Special Gold Medium [or "Small" or "Large"] Pessary 10 Karat"; or "Illinois Special Gold-Filled Pessary Medium [or "Small" or "Large"] Tubular X-Cel."

The article was alleged to be misbranded (1) in that the labeling failed to bear adequate warnings against its use in those pathological conditions where its use might be dangerous to health or against unsafe methods or duration of administration or application; and (2) in that the labeling failed to bear adequate directions for use.

On December 27, 1940, the Illinois Surgical Supply Co., Chicago, Ill., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be relabeled under the supervision of the Food and Drug Administration.

DRUGS SEIZED BECAUSE OF CONTAMINATION WITH FILTH

458. Adulteration of ampuls of triple distilled water. U. S. v. 4 Boxes of Ampuls of Triple Distilled Water. Default decree of condemnation and destruction. (F. D. C. No. 4399. Sample No. 57061–E.)

Samples of this triple distilled water were found to contain viable mold.

On April 18, 1941, the United States attorney for the Eastern District of Missouri filed a libel against 4 boxes, each containing 25 ampuls of triple distilled water at Kirkwood, Mo., alleging that the article had been shipped in interstate commerce on or about March 6, 1941, by the Zeigler Pharmacal Co. from Buffalo, N. Y.; and charging that it was adulterated.

The article was alleged to be adulterated in that it consisted in part of a filthy substance, namely, mold. It was alleged to be adulterated further in that it purported to be a drug the name of which is recognized in an official compendium, the National Formulary, and its quality and purity fell below the standard set forth in such compendium since it contained micro-organisms; whereas the National Formulary requires that triple distilled water shall be free from micro-organisms.

On May 17, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

Nos. 459 and 460 report the seizure and disposition of Hart's Asthma Medicine which was contaminated with mold growth; and the labeling of which failed to bear adequate warning statements and did bear false and misleading therapeutic claims.

459. Adulteration and misbranding of Hart's Compound Asthma Medicine. U. S. v. 96 2-Ounce, 78 4-Ounce, and 113 6-Ounce Packages of Hart's Compound Asthma Medicine. Default decree of condemnation and destruction. (F. D. C. No. 4376. Sample Nos. 55606–E to 55608–E, incl.)

On April 22, 1941, the United States attorney for the District of Oregon filed a libel against the above-named product at Portland, Oreg., alleging that it had been shipped by Hart's Asthma Medicine Co. from Buffalo, N. Y., within the period from on or about March 15, 1940, to on or about January 13, 1941; and charging that it was adulterated and misbranded.

Analysis of a sample of the article showed that it consisted essentially of potassium iodide (approximately 64 grains per fluid ounce), glycerin, water, and flavoring materials including cinnamon and cardamom.

The article was alleged to be adulterated in that it consisted in part of a filthy substance, namely, mold.

It was alleged to be misbranded: (1) In that the labeling failed to bear such adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users. (2) In that representations in the labeling that it would be efficacious in the treatment of asthma, including the relief of paroxysms or spasmodic attacks, bronchial trouble including bronchitis and bronchial colds, and hay fever, and that it would preserve health, were false and misleading since it would not be efficacious for such purposes.

On June 4, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

460. Adulteration and misbranding of Hart's Compound Asthma Medicine. U. S. v. 48 2-Ounce, 24 4-Ounce, and 24 6-Ounce Packages of Hart's Compound Asthma Medicine. Default decree of condemnation and destruction. (F. D. C. No. 4377. Sample No. 55437–E.)

On April 28, 1941, the United States attorney for the Western District of Washington filed a libel against the above-named product at Seattle, Wash., alleging that it had been shipped by McKesson & Robbins from Portland, Oreg., on or about February 26, 1941; and charging that it was adulterated and misbranded.

Analysis of a sample of the article showed that it consisted essentially of potassium iodide, glycerin, water, and flavoring materials, including cardamom and cinnamon.

The article was alleged to be adulterated in that it consisted in part of a filthy substance, namely, mold.

It was alleged to be misbranded: (1) In that the labeling failed to bear such adequate warnings against use in those pathological conditions or by children

where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users. (2) In that representations in the labeling that it would be efficacious in the treatment of asthma, including the relief of paroxysms or spasmodic attacks, bronchial trouble including bronchitis and bronchial colds, and hay fever, and that it would preserve health, were false and misleading since it would not be efficacious for such purposes.

On June 30, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS SEIZED BECAUSE OF FAILURE TO COMPLY WITH OFFICIAL OR OWN STANDARDS OR BECAUSE OF SUBSTITUTION[2]

461. Adulteration and misbranding of ampuls of ephedrine sulfate, quinine dihydrochloride, and pituitary solution. U. S. v. American Parentrasol Laboratories, Inc., and George Blank. Corporation fined $400; George Blank fined $400. (F. D. C. No. 2898. Sample Nos. 54573–D, 55419–D, 55461–D, 14938–E.)

These products were all drugs recognized in the National Formulary and their strength or quality differed from that set forth in that compendium. The ampuls of quinine dihydrochloride also fell below the standard declared on their labels.

On February 13, 1941, the United States attorney for the District of Connecticut filed an information against American Parentrasol Laboratories, Inc., Bridgeport, Conn., and George Blank, alleging shipment within the period from on or about July 12, 1939, to on or about May 24, 1940, from the State of Connecticut into the States of Michigan and Pennsylvania of quantities of the above-named drugs which were adulterated and misbranded.

The ephedrine sulfate was alleged to be adulterated in that it purported to be or was represented as ampuls of ephedrine sulfate, a drug the name of which is recognized in the National Formulary, and its strength differed from or its quality fell below the standard set forth in that compendium since it yielded an amount of ephedrine corresponding to less than 72.6 percent, namely, not more than 58.4 percent of the labeled amount of ephedrine sulfate; whereas the National Formulary provides that ampuls of ephedrine sulfate shall yield an amount of ephedrine corresponding to not less than 72.6 percent of the labeled amount of ephedrine sulfate. It was alleged to be misbranded in that the statements, (ampul) "1 c.c.—¾ gr. Ephedrine" and (box) "1 c.c.—¾ gr. Ephedrine Sulphate," were false and misleading, since each cubic centimeter of the article did not contain ¾ grain but did contain a smaller amount, namely, slightly more than ⅔ grain of ephedrine, and each cubic centimeter did not contain ¾ grain of ephedrine sulfate but did contain a smaller amount, namely, approximately 0.6 grain of ephedrine sulfate.

The quinine dihydrochloride was alleged to be adulterated in that it purported to be or was represented as ampuls of quinine dihydrochloride, a drug the name of which is recognized in the National Formulary, and its strength differed from or its quality fell below the standard set forth in that compendium in that it yielded less than 95 percent, namely, approximately 55.3 percent of the labeled amount of quinine dihydrochloride; whereas the National Formulary provides that ampuls of quinine dihydrochloride shall yield not less than 95 percent of the labeled amount of quinine dihydrochloride, and its difference in strength or quality from such standard was not plainly stated on its label. It was alleged to be misbranded in that the statements, (ampul) "1 c. c. Quinine Dihydrochloride 7½ grs." and (box) "1 c. c. Quinine Di HCL * * * 7½ grs.," were false and misleading, since each cubic centimeter of the article contained less than 7½ grains, namely, 4.15 grains of quinine dihydrochloride.

The pituitary solution was alleged to be adulterated in that it purported to be or was represented as ampuls of posterior pituitary, a drug the name of which is recognized in the National Formulary, and its strength differed from or its quality fell below the standard set forth in that compendium, since 1 cubic centimeter produced an activity upon the isolated uterus of a virgin guinea pig corresponding to less than 80 percent, namely, not more than 62½ percent of that produced by 0.005 gram of the standard powdered posterior pituitary; whereas the National Formulary provides that unless otherwise stated on the label, ampuls of posterior pituitary contain measured quantities of sterile

[2] See also Nos. 426, 429, 436, 446, 449, 458.

liquor pituitarii posterii, a drug recognized in the United States Pharmacopoeia, which provides that 1 cubic centimeter of solution of posterior pituitary shall produce an activity upon the isolated uterus of a virgin guinea pig corresponding to not less than 80 percent of that produced by 0.005 gram of the standard powdered posterior pituitary.

The information also charged the shipment in interstate commerce in violation of the Food and Drugs Act of 1906 of a quantity of Ovestrin in Oil which was adulterated and misbranded, as reported in N. J. No. 31136 published under that act.

On May 6, 1941, pleas of nolo contendere having been entered on behalf of the defendants, the court imposed a fine of $400 on the corporation and $400 on George Blank. (Both defendants were fined $100 on the counts charging violation of the Food and Drugs Act, but imposition of the sentence was suspended with respect to George Blank on these counts and he was placed on probation for a period of 2 years.)

462. Adulteration and misbranding of ammoniated mercury ointment, phenobarbital and atropine sulfate tablets, and Vitaphosphates. U. S. v. Physicians Drug & Supply Co. Plea of nolo contendere. Fine, $500. (F. D. C. No. 2843. Sample Nos. 14174-E, 14476-E, 14477-E, 14492-E.)

The ammoniated mercury ointment contained a smaller proportion of mercury than that required by the standard set forth in the United States Pharmacopoeia and of that declared on its label; the phenobarbital and atropine sulfate tablets contained no phenobarbital and no atropine sulfate, but did contain $\frac{1}{33}$ grain of strychnine sulfate; and the Vitaphosphates contained approximately only one-eighth the amount of vitamin B_1 declared on the label.

On December 4, 1940, the United States attorney for the Eastern District of Pennsylvania filed an information against Physicians Drug & Supply Co., a corporation at Philadelphia, Pa., alleging shipment on or about April 16 and 30, 1940, from the State of Pennsylvania into the State of New Jersey, of quantities of the above-named drugs that were adulterated and misbranded.

The ammoniated mercury ointment was alleged to be adulterated in that it purported to be a drug the name of which is recognized in the United States Pharmacopoeia, 11th Revision, but its strength differed from the standard set forth in such compendium in that it contained ammoniated mercury corresponding to not more than 3.22 percent of mercury; whereas the pharmacopoeia provides that ammoniated mercury ointment shall contain ammoniated mercury corresponding to not less than 7.1 percent of mercury, and the respect in which its strength differed from such standard was not stated plainly on the label. It was alleged to be misbranded in that the statement "Ammoniated Mercury Ointment Five (5%) Per Cent," borne on the jar label, was false and misleading since it did not contain 5 percent of ammoniated mercury but did contain a smaller amount, namely, not more than 4.1 percent of ammoniated mercury.

The phenobarbital and atropine sulfate tablets were alleged to be adulterated in that their strength differed from and their purity or quality fell below that which they purported or were represented to possess, since each of said tablets was represented to contain $\frac{1}{4}$ grain of phenobarbital and $\frac{1}{300}$ grain of atropine sulfate, whereas they contained no phenobarbital and no atropine sulfate but did contain approximately $\frac{1}{33}$ grain of strychnine sulfate. They were alleged to be adulterated further in that tablets each containing approximately $\frac{1}{33}$ grain of strychnine sulfate had been substituted in whole or in part for tablets each containing $\frac{1}{4}$ grain of phenobarbital and $\frac{1}{300}$ grain of atropine sulfate, which they purported to be. They were alleged to be misbranded in that the statement, "Each Tablet Contains: Phenobarbital Gr. $\frac{1}{4}$ * * * Atropine Sulphate Gr. $\frac{1}{300}$," borne on the bottle label, was false and misleading since the said tablets contained no phenobarbital and no atropine sulfate but did contain approximately $\frac{1}{33}$ grain of strychnine sulfate. They were alleged to be misbranded further in that tablets each containing approximately $\frac{1}{33}$ grain of strychnine sulfate had been offered for sale under the name of another drug.

The drug Vitaphosphates was alleged to be adulterated in that its strength differed from or its quality or purity fell below that which it purported or was represented to possess, in that each fluid ounce was represented to contain 400 U. S. P. units of vitamin B_1; whereas each fluid ounce contained less than 400 U. S. P. units, namely, not more than 50 U. S. P. units, of vitamin B_1. It was alleged to be misbranded in that the statement "Each Fluid Ounce Contains: Vitamin B_1 400 units," borne on the bottle label, was false and misleading

since each fluid ounce did not contain 400 U. S. P. units of vitamin B_1 but did contain a smaller amount.

On February 28, 1941, a plea of nolo contendere was entered on behalf of the defendant and the court imposed a fine of $500.

463. Adulteration of chloroform. U. S. v. 795 Bottles and 972 Bottles of Chloroform. Default decrees of condemnation. Portion of product ordered destroyed; remainder ordered delivered to a hospital to be used for technical purposes. (F. D. C. Nos. 5174, 5180. Sample Nos. 47480–E, 50848–E.)

This product differed from the pharmacopoeial standards because of the presence of carbonizable substances in both lots and of chlorinated decomposition products in one.

On July 19 and 22, 1941, the United States attorneys for the District of Maryland and the Northern District of Illinois filed libels against 972 bottles of chloroform at Perry Point, Md., and 795 bottles of chloroform at Chicago, Ill., alleging that the article had been shipped in interstate commerce on or about May 27, 1941, by the City Chemical Corporation from New York, N. Y., and Jersey City, N. J.; and charging that it was adulterated and misbranded. It was labeled in part: "Chloroform USP XI (Not for Anesthesia)."

The article was alleged to be adulterated in that it purported to be or was represented as a drug the name of which is recognized in the United States Pharmacopoeia and its strength differed from and its quality and purity fell below the standard set forth in that compendium since it contained carbonizable substances and in one lot chlorinated decomposition products. It was alleged to be misbranded in that the statement "Chloroform USP XI," borne on the label, was false and misleading.

On September 20 and October 15, 1941, no claimant having appeared, judgments of condemnation were entered and the goods seized at Chicago were ordered destroyed and those seized at Perry Point were ordered delivered to a hospital. The latter lot was relabeled by obliterating the term "U. S. P." and stamping on the label the words, "For technical uses only."

464. Adulteration of powdered extract of digitalis. U. S. v. 1 Can of Powdered Extract of Digitalis. Default decree of condemnation and destruction. (F. D. C. No. 3742. Sample No. 25065–E.)

This product possessed a potency of not more than 1.3 U. S. P. digitalis units per 0.1 gram; whereas the National Formulary provides that it should possess a potency of not less than 2.75 U. S. P. digitalis units per 0.1 gram. Moreover, it was invoiced as "P. E. Digitalis 1–4," which meant that each gram should possess an activity of not less than 4 U. S. P. digitalis units.

On January 31, 1941, the United States attorney for the Eastern District of Pennsylvania filed a libel against 1 can of powdered extract of digitalis at Philadelphia, Pa., alleging that the article had been shipped in interstate commerce on or about November 2, 1940, by J. L. Hopkins & Co. from New York, N. Y.; and charging that it was adulterated. It was labeled in part: "Powdered Extract Not Biologically Tested Defatted Digitalis * * * Not N. F."

The article was alleged to be adulterated in that it purported to be or was represented as a drug the name of which is recognized in the National Formulary, an official compendium, but its strength differed from the standard set forth in such compendium and its difference in strength from such standard was not stated on its label. It was alleged to be adulterated further in that a substance, namely, a preparation of digitalis possessing a potency of not more than 1.3 U. S. P. digitalis units per 0.1 gram had been substituted therefor.

On March 8, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

465. Adulteration and misbranding of powdered extract digitalis leaves. U. S. v. 1 Can of Powdered Extract Digitalis Leaves. Consent decree of condemnation and destruction. (F. D. C. No. 2156. Sample Nos. 3014–E, 3060–E.)

This product possessed a potency of 1.6 U. S. P. digitalis units per 0.1 gram, whereas the National Formulary requires that extract of digitalis possess a potency of not less than 2.75 U. S. P. digitalis units per 0.1 gram.

On June 4, 1940, the United States attorney for the Western District of Pennsylvania filed a libel against one can of powdered extract digitalis leaves at Pittsburgh, Pa., alleging that the article had been shipped in interstate commerce on or about September 27, 1939, by S. B. Penick & Co. from Jersey City, N. J.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium.

It was alleged to be misbranded in that the statement on the label, "Extract Tested N. F.," was false and misleading since the said statement represented that the article was a drug the name of which is recognized in the National Formulary; whereas its strength differed from the standard set forth in that compendium.

On September 30, 1941, the claimant having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

466. Adulteration of tincture of digitalis. U. S. v. 6 Bottles of Tincture Digitalis U. S. P. Default decree of condemnation and destruction. (F. D. C. No. 4830. Sample No. 39804–E.)

Examination of this product showed that its potency was not more than 63 percent of the U. S. Pharmacopoeia XI minimum requirement.

On May 24, 1941, the United States attorney for the Eastern District of Missouri filed a libel against 6 pint bottles of tincture of digitalis at St. Louis, Mo., alleging that the article had been shipped by Eli Lilly & Co. from Indianapolis, Ind., on or about October 22, 1940, and February 21, 1941; and charging that it was adulterated in that it purported to be a drug the name of which was recognized in an official compendium, namely, the United States Pharmacopoeia, but its strength fell below the standard set forth in such compendium.

On June 18, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

467. Adulteration and misbranding of triple distilled water. U. S. v. 180 Ampuls, 2,740 Ampuls, and 70 Bottles of Triple Distilled Water. Default decree of condemnation and destruction. ((F. D. C. No. 5159. Sample Nos. 11275–E, 11276–E, 11277–E.)

These ampuls of distilled water failed to conform to the requirements of the National Formulary for hydrogen ion concentration and a portion were short of the declared volume and were not packaged as required by the formulary. The water in the bottles contained as much as 11 times the maximum amount of oxidizable substances permitted by the National Formulary.

On or about July 18, 1941, the United States attorney for the Southern District of Texas filed a libel against 2,920 10-cc. ampuls and 70 100-cc. bottles of triple distilled water at Houston, Tex., alleging that the article had been shipped in interstate commerce within the period from on or about March 29 to on or about May 22, 1941, by Diarsenol Co., Inc., from Buffalo, N. Y.; and charging that it was adulterated and misbranded.

The product contained in the ampuls was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the National Formulary, an official compendium, but its quality fell below the standard set forth therein since it failed to comply with the National Formulary requirement for pH (hydrogen ion concentration). The product contained in the bottles was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the National Formulary, an official compendium, and its purity and quality fell below the standard set forth therein since, when 100 cubic centimeters of the article was heated to boiling, acidulated with 10 cubic centimeters of diluted sulfuric acid, and 0.1 cubic centimeter of twentieth-normal potassium permanganate was added, the color of the liquid completely disappeared after boiling for 10 minutes; whereas the National Formulary requires that when 100 cubic centimeters of distilled water is heated to boiling, is acidulated with 10 cubic centimeters of diluted sulfuric acid, and 0.1 cubic centimeter of twentieth-normal potassium permanganate is added, it does not become completely decolorized after boiling for 10 minutes.

A portion of the article contained in the ampuls was alleged to be misbranded in that the statement "10 cc" on the ampuls was false and misleading since a portion of the ampuls contained less than 10 cubic centimeters of water; and in that it purported to be a drug the name of which is recognized in the National Formulary and was not packaged as therein prescribed.

On August 22, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

468. Adulteration and misbranding of Petrodine and Special Formula No. 2389 Ampoules; misbranding of Klorseptic Oil and Klorseptic Ointment. U. S. v. Howard D. Day (High Chemical Co.). Plea of guilty. Fine, $400. (F. D. C. No. 2886. Sample Nos. 10266–E, 69883–D, 69890–D, 77846–D.)

On April 18, 1941, the United States attorney for the Eastern District of Pennsylvania filed an information against Howard D. Day, trading as the High Chemical Co. at Philadelphia, Pa., alleging shipment within the period from on or about January 12 to on or about February 14, 1940, from the State of Pennsylvania into the States of New York and New Jersey of quantities of the above-named products of which portions were adulterated and misbranded and the remainder was misbranded. The Petrodine was labeled in part: "Petrodine * * * Mineral Oil with Iodine * * * Prepared only by Iodine Products Co. * * * Philadelphia, Pa."

The Petrodine was alleged to be adulterated in that its strength differed from and its quality or purity fell below that which it purported or was represented to possess, in that it was represented to contain 0.2 grain of elementary iodine per fluid ounce; whereas it contained not more than 0.09 grain of elementary iodine per fluid ounce. It was alleged to be misbranded in that the statement "* * * containing 0.2 gr. elementary iodine to the fluid ounce," borne on the label, was false and misleading.

The Special Formula No. 2389 Ampoules were alleged to be adulterated in that their strength differed from and their quality or purity fell below that which they purported or were represented to possess, in that the contents of each of the ampuls was represented to consist of a solution containing 1 grain of lecithin per cubic centimeter; whereas the contents of each ampul contained not more than 0.338 grain of lecithin per cubic centimeter. The article was alleged to be misbranded in that the statement "Ampoules * * * Lecithin * * * 1 gr. * * * 1 cc," on the box label, was false and misleading.

Analysis of a sample of the Klorseptic Oil showed that it consisted essentially of a semi-viscous oil having the odor of eucalyptus oil and containing an organic chloride; and that it contained no free chlorine.

The Klorseptic Oil was alleged to be misbranded: (1) In that the statements "Klorseptic Oil is a * * * Chlorinated topical dressing * * * containing approximately 25% chlorine," appearing in the labeling, were misleading since it contained no free chlorine. (2) In that the following statements in the labeling, "Useful as a topical dressing in burns, infected wounds, both superficial and deep, Otitis Media, and skin lesions," were false and misleading since they represented that it would be efficacious as a topical dressing in burns, infected wounds, both superficial and deep, and that it would be efficacious as an adequate treatment of otitis media and skin lesions; whereas it would not be efficacious for such purposes.

Examination of a sample of Klorseptic Ointment showed that it was an amber-colored ointment having a eucalyptus odor; analysis showed that it contained no free chlorine. It was alleged to be misbranded in that the following statements in the labeling, "Useful in some forms of wounds, lacerations, abrasions, burns and wherever topical dressing is indicated," were false and misleading since they represented that it would be useful in the treatment of wounds, lacerations, abrasions, burns, and wherever a topical dressing is indicated; whereas it would not be useful in the treatment of some forms of wounds, lacerations, abrasions, burns or wherever a topical dressing is indicated.

On May 21, 1941, the defendant entered a plea of guilty and the court imposed a fine of $400.

469. Adulteration and misbranding of mercurochrome. U. S. v. Max Mirkis (Southeastern Chemical Co. and Carolina Vinegar Co.). Plea of nolo contendere. Fine, $50. (F. D. C. No. 2904. Sample No. 20554–E.)

On January 2, 1941, the United States attorney for the Southern District of Florida filed an information against Max Mirkis, trading as the Southeastern Chemical Co. and Carolina Vinegar Co. at Jacksonville Fla., alleging delivery, on or about February 9, 1940, for introduction in interstate commerce from the State of Florida into the State of Georgia of a quantity of mercurochrome that was adulterated and misbranded. It was labeled in part: "Mercurochrome 2% Solution H. W. & D. SCC * * * Prepared from Genuine Mercurochrome."

The article was alleged to be adulterated in that its strength differed from or its quality fell below that which it purported to possess in that it was represented to contain 2 percent of mercurochrome; whereas it contained not more than 1.21 percent of mercurochrome. It was alleged to be misbranded in that

the statement "Mercurochrome 2% Solution," appearing on the label, was false and misleading.

On January 13, 1941, the defendant entered a plea of nolo contendere and the court imposed a fine of $50.

470. Adulteration and misbranding of barbital tablets, cough tablets, conjunctivitis tablets, and equine worm powder; misbranding of eye ointment. U. S. v. Lloyd M. Curts and Charles D. Folse (Curts-Folse Laboratories). Pleas of guilty. Fine, $1 and costs. (F. D. C. No. 2861. Sample Nos. 4466–E, 4467–E, 4468–E, 16018–E, 16739–E.)

All of these veterinary products contained smaller amounts of certain ingredients than those declared on their labels. Furthermore, the labels of the cough tablets, the conjunctivitis tablets, the eye ointment, and the equine worm powder contained false and misleading representations regarding their efficacy in the treatment of certain diseases of animals.

On January 10, 1941, the United States attorney for the District of Kansas filed an information against Lloyd M. Curts and Charles D. Folse, trading as Curts-Folse Laboratories at Kansas City, Kans., alleging shipment on or about August 29 and November 29, 1939, from the State of Kansas into the State of Illinois of a quantity of barbital tablets, cough tablets, and conjunctivitis tablets that were adulterated and misbranded, and on or about October 6, 1939, and February 26, 1940, from the State of Kansas into the State of Oklahoma of a quantity of eye ointment that was misbranded and of equine worm powder that was both adulterated and misbranded.

The articles were labeled in part: "Barbital Tablets 1½ grs. Cu-Fo Dose Dogs and Cats 1½ to 10 grains"; "Cough Tablets Small Animals Ammon Chloride 1 gr. * * * Dose Dogs and Cattle"; "Conjunctivitis Tablets No. 1 Contains Boric Acid ½ gr. Salicylic Acid 2 grs. Zinc Sulphate 1 gr. * * * for eye wash"; "Eye Ointment * * * Distributed by Barber and Cochran * * * Oklahoma City, Okla."; "Equine Worm Powder Contains * * * Arsenic 2%."

The barbital tablets were alleged to be adulterated in that their strength differed from that which they purported or were represented to possess in that each of said tablets was represented to contain 1½ grains of barbital; whereas each tablet contained not more than 1.18 grains of barbital. They were alleged to be misbranded in that the statement "Barbital Tablets 1½ grs.," borne on the bottle label, was false and misleading since each of the tablets did not contain 1½ grains of barbital but did contain a smaller amount.

Analysis of a sample of the cough tablets showed that they consisted essentially of ammonium chloride (0.76 grain per tablet) and extracts of plant material, including licorice. They were alleged to be adulterated in that their strength differed from that which they purported or were represented to possess in that each of said tablets was represented to contain 1 grain of ammonium chloride; whereas each tablet contained less than 1 grain, namely, not more than 0.76 grain of ammonium chloride. They were alleged to be misbranded in that the statement "Tablets * * * Contain Ammon Chloride 1 gr.," borne on the bottle label, was false and misleading since each of the tablets did not contain 1 grain of ammonium chloride but did contain a smaller amount. They were alleged to be misbranded further in that the statement "Cough Tablets * * * Cattle," borne on the bottle label, was false and misleading since the tablets would not be efficacious in the treatment of coughs in cattle.

Analysis of a sample of the conjunctivitis tablets showed that each of them consisted essentially of boric acid (0.45 grain), salicylic acid (1.48 grains), zinc sulfate (0.73 grain), and methylene blue. They were alleged to be adulterated in that their strength differed from that which they purported or were represented to possess in that each of said tablets was represented to contain ½ grain of boric acid, 2 grains of salicylic acid, and 1 grain of zinc sulfate; whereas each of said tablets contained not more than 0.45 grain of boric acid, not more than 1.48 grains of salicylic acid, and not more than 0.73 grain of zinc sulfate. They were alleged to be misbranded in that the statement "Tablets * * * Contains Boric Acid ½ gr. Salicylic Acid 2 grs. Zinc Sulfate 1 gr.," borne on the bottle label, was false and misleading since each of said tablets contained less than ½ grain of boric acid, less than 2 grains of salicylic acid, and less than 1 grain of zinc sulfate. They were alleged to be misbranded further in that the statement "Conjunctivitis," borne on the bottle label, was false and misleading since said drug would not be efficacious in the treatment of conjunctivitis.

Analysis of a sample of the eye ointment showed that it consisted essentially of yellow mercuric oxide incorporated in a suitable base. It was alleged to be misbranded in that the statement "For the treatment of eye inflammations and infections * * * If the eye contains pus," borne on the cartons, was false and misleading since it would not be efficacious for the treatment of eye inflammations and infections or of pus in the eye.

Analysis of a sample of the equine worm powder showed that it consisted essentially of arsenic trioxide (1.57 percent), plant material including areca nuts and tobacco, compounds of sodium, iron, and calcium, chlorides, sulfates, and phosphates. It was alleged to be adulterated in that its strength differed from or its quality or purity fell below that which it purported or was represented to possess in that it was represented to contain 2 percent of arsenic, i. e., arsenic trioxide; whereas it contained less than 2 percent, namely, not more than 1.57 percent of arsenic trioxide. It was alleged to be misbranded in that the statements "Equine Worm Powder" and "Contains * * * Arsenic 2%," appearing on the label, were false and misleading since it was not efficacious in the treatment of worms in horses and it did not contain 2 percent of arsenic trioxide, but did contain a smaller amount.

On January 28, 1941, the defendants entered pleas of guilty and the court imposed a fine of $1 and costs to be paid jointly.

471. Adulteration and misbranding of sodium cacodylate solution, calcium gluconate compound solution, and liquid nux vomica alkaloids. U. S. v. 14 Bottles of Sodium Cacodylate Solution, 68 Bottles of Calcium Gluconate Compound Solution, and 8 Bottles of Liquid Nux Vomica Alkaloids. Default decree of destruction. (F. D. C. Nos. 3710 to 3712, incl. Sample Nos. 43057–E, 43061–E, 43076–E.)

On January 27, 1941, the United States attorney for the Northern District of Oklahoma filed a libel against the above-named products at Tulsa, Okla., alleging that they had been shipped from Kansas City, Mo., by the Peerless Serum Co. of Kansas City, Kans., on or about August 22 and October 5 and 26, 1940; and charging that they were adulterated and misbranded.

Analysis of a sample of the sodium cacodylate solution showed that it contained not more than 2.6 grains of sodium cacodylate per cubic centimeter. It was alleged to be adulterated in that its strength differed from that which it was purported or was represented to possess, namely, "Sodium Cacodylate Solution 4.5 Gr. per cc." It was alleged to be misbranded in that statements on the label, "Sodium Cacodylate Solution 4.5 Gr. per cc.," and "Useful in the treatment of Anaplasmosis, Swamp Fever, Anemia, Influenza, Shipping Fever, Chronic Skin Diseases, and to build up Convalescent Patients," were false and misleading since it did not constitute an effective treatment for the diseases named on the label.

Analysis of a sample of the calcium gluconate solution showed that it contained approximately 15 percent of calcium gluconate. It was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely, "Calcium Gluconate Comp. Solution * * * 23% Solution." It was alleged to be misbranded in that the statements on the label, "Calcium Gluconate Comp. Solution * * * 23% Solution," and "Indications: * * * Azoturia," were false and misleading since it did not contain 23 percent of calcium gluconate and did not constitute an adequate treatment for azoturia.

Analysis of a sample of the nux vomica alkaloids liquid showed that it contained per cubic centimeter approximately 0.15 grain (less than 1/6 grain) of strychnine sulfate, and approximately 0.045 grain (approximately 1/22 grain) of brucine sulfate. It was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely, "Each cc. contains a quarter grain each of Strychnine Sulphate and Brucine Sulphate." It was alleged to be misbranded in that the above-quoted statement was false and misleading since it contained materially less than ¼ grain each of strychnine sulfate and brucine sulfate per cubic centimeter.

On February 24, 1941, no claimant having appeared, judgment was entered ordering that the products be destroyed.

472. Adulteration and misbranding of Mineralvita. U. S. v. 99 Bottles of Mineralvita. Default decree of condemnation and destruction. ((F. D. C. No. 3887. Sample No. 31578–E.)

On February 27, 1941, the United States attorney for the Eastern District of Michigan filed a libel against 99 bottles of Mineralvita at Pontiac, Mich., alleg-

ing that the article had been shipped by the Mineralvita Sales Co. from Toledo, Ohio, on or about February 1 and 3, 1941; and charging that it was adulterated and misbranded.

Analysis of a sample of the article showed that it consisted essentially of sodium sulfate (1.3 percent), and slaked lime (0.9 percent), and that it contained but inconsequential traces of, if any, manganese peptonate, lithium carbonate, calcium phosphate, manganese sulfate, dipotassium phosphate, disodium phosphate, lithium bromide, magnesium glycerophosphate, ferric phosphate, and magnesium chloride.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported or was represented to possess, in that the labeling bore representations that minerals including manganese peptonate, lithium carbonate, calcium phosphate, manganese sulfate, dipotassium phosphate, disodium phosphate, lithium bromide, magnesium glycerophosphate, ferric phosphate, and magnesium chloride had been added thereto, whereas it contained but inconsequential traces, if any, of the above-named minerals; in that representations in the labeling (leaflet) that it had always been a source of precious minerals such as calcium phosphate and ferric phosphate, and that 4 ounces four times a day in combination with regular meals would furnish young and old their daily requirement of minerals including phosphorus, whereas it contained no phosphorus, no significant proportion of calcium phosphate or ferric phosphate and could not be depended upon to supply the various minerals which might be deficient in the daily diet; and that Mineralvita had been scientifically blended with the minerals found in the human system and then treated by a form of electrolysis which prepared them for assimilation into the blood stream, whereas it had not been scientifically blended with the minerals found in the human system, and treatment by electrolysis, if used, would not separate and prepare any of its minerals for entry into the human system nor make them readily assimilated into the blood stream.

It was alleged to be misbranded: (1) In that the statement on the bottle label, "Minerals Added Manganese peptonate Lithium carbonate Calcium oxide Calcium phosphate Manganese sulphate Potassium iodide Di Potassium phosphate Potassium chloride Di Sodium phosphate Lithium Bromide Magnesium glycerophosphate Calcium gluconate Ferric Phosphate Magnesium chloride Sodium sulphate Artificial coloring," was false and misleading since it contained but inconsequential proportions of, or no, manganese peptonate, lithium carbonate, calcium phosphate, manganese sulfate, dipotassium phosphate, disodium phosphate, lithium bromide, magnesium glycero-phosphate, ferric phosphate, or magnesium chloride. (2) In that the statement in the labeling "treated by * * * electrolysis" was false and misleading since the labeling failed to reveal the material fact that any treatment by electrolysis to which the water may have been subjected had not affected its composition or quality in any material manner. (3) In that the designation "Mineralvita" on the bottle label and shipping case and the statement on the shipping case label, "Manufactured from Nature's Minerals to Promote Health and Strength," was false and misleading since it did not contain life minerals, was not manufactured from natural minerals, and could not be depended upon to promote health and strength.

On April 4, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

473. Adulteration and misbranding of Virgitalis Digitalis Lanata Tablets. U. S. v. 7 Bottles of Virgitalis Digitalis Lanata Tablets. Default decree of condemnation and destruction. (F. D. C. No. 3902. Sample Nos. 50070-E, 50095-E.)

The labeling of this product represented that it possessed per gram (approximately 1½ grains) an activity equivalent to not less than 1 U. S. P. unit of digitalis; whereas it possessed an activity not greater than ⅓ U. S. P. unit of digitalis.

On March 3, 1941, the United States attorney for the District of Columbia filed a libel against the above-named product at Washington, D. C., alleging that it had been shipped by Van Pelt & Brown, Inc., on or about January 8, 1941, from Richmond, Va.; and charging that it was adulterated and misbranded. It was labeled in part: "Tablets Virgitalis Digitalis Lanata * * * Each Tab'et Assays * * * 1½ grains Standardized Whole Digitalis Leaf (Physiologically Standardized)."

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely, "Each Tablet

Assays * * * 1½ grains Standardized Whole Digitalis Leaf (Physiologically Standardized)." It was alleged to be misbranded in that the above-quoted statement was false and misleading.

On March 21, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

474. Adulteration of sassafras oil. U. S. v. 49 Pounds of an Article Labeled in Part "Oil Sassafras Natural." Default decree of condemnation and destruction. (F. D. C. No. 3682. Sample No. 10873–E.)

This product was not sassafras oil but was a mixture of oils obtained from sources other than sassafras including a small proportion of methyl salicylate.

On January 23, 1941, the United States attorney for the Southern District of New York filed a libel against 49 pounds of sassafras oil at New York, N. Y., alleging that the article had been shipped in interstate commerce on or about January 1, 1941, by M. E. Proffitt from Johnson City, Tenn.; and charging that it was adulterated and misbranded. It was labeled in part: "Southern Oleum Sassafras, U. S. P."

The article was alleged to be adulterated in that a substance, namely, a mixture of oils other than sassafras oil, had been substituted wholly or in part therefor.

It was alleged to be misbranded in that the statement on the label, "Oil Sassafras Natural," was false and misleading as applied to this article, which was not the article described in the United States Pharmacopoeia under the title "Oleum Sassafras," subtitle "Oil of Sassafras."

On February 15, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

VITAMIN PREPARATIONS

475. Adulteration and misbranding of Vitamin A–D Tablets. U. S. v. 15 Cartons of Vitamin A–D Tablets. Default decree of condemnation and destruction. (F. D. C. No. 5154. Sample No. 65018–E.)

Each of these tablets was represented to contain 3,150 U. S. P. units of vitamin A, but biological examination showed that they contained not more than 2,500 U. S. P. units of vitamin A per tablet.

On July 15, 1941, the United States attorney for the District of Colorado filed a libel against 15 cartons each containing 90 Vitamin A–D Tablets at Denver, Colo., which had been consigned by Bleything Laboratories, alleging that the article had been shipped from Los Angeles, Calif., on or about March 7 and 11, 1941; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess. It was alleged to be misbranded in that the statement on the label, "Each tablet contains not less than 3,150 U. S. P. units of vitamin 'A'," was false and misleading.

It was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2991.

On September 17, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

476. Adulteration and misbranding of Hain Becompx Capsules. U. S. v. 56 Packages of Hain Becompx Capsules. Default decree of condemnation and destruction. (F. D. C. No. 4375. Sample No. 32497–E.)

This product was represented to contain 100 International Units of vitamin B_1 per capsule. Biological assay, however, showed that it contained not more than 60 U. S. P. units of vitamin B_1 per capsule (1 U. S. P. unit is equivalent to 1 International Unit of vitamin B_1).

On April 17, 1941, the United States attorney for the Southern District of California filed a libel against 56 packages of Hain Becompx Capsules, alleging that the article had been shipped in interstate commerce on or about December 9, 1940, by the International Vitamin Corporation from Brooklyn, N. Y.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, namely, "Each capsule contains: B_1—100 International (200 Sherman) Units." The article was alleged to be misbranded in that the following statements appearing on the box were false and misleading since they were incorrect: "Each Capsule contains: B_1—100 International (200 Sherman) Units." The article was also charged to

be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2821.

On June 16, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

477. Adulteration and misbranding of R M Dietary Supplements Vitamin A and D. U. S. v. 38 Bottles of R M Dietary Supplements Vitamin A and D. Default decree of condemnation. Product ordered distributed to hospitals. (F. D. C. No. 4304. Sample No. 8319-E.)

This product was represented to contain 3,140 International Units of vitamin A and 314 International Units of vitamin D per tablet, but contained not more than 30 U. S. P. units of vitamin A and not more than 150 U. S. P. units of vitamin D. (By definition, 1 U. S. P. unit of vitamin A or D is equivalent to 1 International Unit of the same vitamin.) A large core of cotton extended more than halfway to the bottom of the bottle and tablets surrounded the cotton. When the cotton was removed, the tablets filled the bottle approximately half full.

On April 12, 1941, the United States attorney for the District of Minnesota filed a libel against 38 bottles of the above-named product at Minneapolis, Minn., alleging that the article had been shipped in interstate commerce on or about November 2, 1940, by Ryer Mouser from Los Angeles, Calif.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess.

It was alleged to be misbranded in that the following statements appearing on the label were false and misleading: "Each Tablet Contains Vitamin A from fish liver oil * * * 3140 I. U. Vitamin D from fish liver oil 314 I. U." It was alleged to be misbranded further in that its container was so filled as to be misleading.

It was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods reported in F. N. J. No. 2549.

On May 29, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered distributed to hospitals chosen by the marshal in his discretion.

478. Adulteration and misbranding of Vi-An Tablets. U. S. v. 30 Bottles and 24 Bottles of Vi-An Tablets. Default decree of condemnation and destruction. (F. D. C. No. 3821. Sample No. 55245-E.)

Each of these tablets was represented to contain 1,250 International Units of vitamin A and 125 International Units of vitamin D, but biological assay showed that they contained not more than 40 International Units of vitamin A and 60 International Units of Vitamin D.

On February 14, 1941, the United States attorney for the Western District of Washington filed a libel against the above-named product at Seattle, Wash., alleging that it had been shipped by Vegetrates, Inc., from Los Angeles, Calif., on or about November 29, 1940; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess. It was alleged to be misbranded in that the statement "Four tablets a day * * * furnish: Vitamin A . . . 5,000 I. U. * * * Vitamin D . . . 500 I. U." was false and misleading since it was incorrect.

It also was alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2822.

On April 24, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

479. Adulteration and misbranding of poultry cod-liver oil. U. S. v. 19 Drums of Cod-Liver Oil. Consent decree of condemnation. Product ordered released under bond for relabeling. (F. D. C. No. 4073. Sample No. 38450-E.)

This product was labeled as containing 400 A. O. A. C. chick units of vitamin D per gram, but contained not more than 320 such units per gram.

On March 28, 1941, the United States attorney for the District of Minnesota filed a libel against 19 drums of cod-liver oil at Minneapolis, Minn., alleging that the article had been shipped in interstate commerce on or about July 17, 1940, by the New England By-Products Corporation from Gloucester, Mass.; and charging that it was adulterated and misbranded. The article was labeled in part: "Gorton's G P Cod Liver Oil Fortified."

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess. It was alleged to be misbranded in that the following statement was false since it was incorrect: "400 Units Vitamin D Per Gram A O A C."

The article was also alleged to be adulterated and misbranded in violation of the provisions of the law applicable to foods reported in F. N. J. No. 2156.

On July 3, 1941, the Gorton Pew Fisheries Co., Gloucester, Mass., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be relabeled under the supervision of the Food and Drug Administration.

480. Adulteration and misbranding of cod-liver oil concentrate. U. S. v. 1¼ 420-Pound Drums of Five X Concentrate. Default decree of condemnation and destruction. (F. D. C. No. 3478. Sample No. 34377–E.)

This product contained less than 300 A. O. A. C. chick units of vitamin D per gram; whereas its label represented that it contained not less than 425 A. O. A. C. chick units of vitamin D per gram.

On December 4, 1940, the United States attorney for the District of New Jersey filed a libel against 1¼ 420-pound drums of cod-liver oil concentrate at Plainfield, N. J., alleging that the article had been shipped in interstate commerce on or about September 9, 1940, by the Whitmoyer Laboratories, Inc., from Myerstown, Pa.; and charging that it was adulterated and misbranded. The article was labeled in part: "Whitmoyer Quality Five X Concentrate."

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess. It was alleged to be misbranded in that the statement on the label, "Five X Concentrate is guaranteed to contain not less than 425 A. O. A. C units vitamin D per gram," was false and misleading since it was incorrect.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2647.

On June 2, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

481. Adulteration and misbranding of fortified cod-liver oil. U. S. v. Seaboard Supply Co., Inc. Plea of nolo contendere. Fine, $150. (F. D. C. No. 2890. Sample Nos. 1236–E, 14209–E, 78465–D.)

This veterinary product was found to be deficient in both vitamin D and vitamin A.

On January 8, 1941, the United States attorney for the Eastern District of Pennsylvania filed an information against Seaboard Supply Co., Inc., a corporation, Philadelphia, Pa., alleging shipment within the period from on or about January 2 to on or about March 28, 1940, from the State of Pennsylvania into the States of West Virginia and Delaware of quantities of fortified cod-liver oil that was adulterated and misbranded. The article was labeled in part: "50 Lbs. Net Sea–Clo–400–D Highly Fortified Cod Liver Oil In Dry Base."

It was alleged to be adulterated in that its strength differed from, or its quality fell below, that which it purported or was represented to possess since it was represented to contain 400 units of vitamin D per gram, and approximately 1,000 units of vitamin A per gram; whereas it contained less than 400 units of vitamin D per gram, namely, less than 200 units of vitamin D per gram, and materially less than 1,000 units of vitamin A per gram, namely, not more than 500 units of vitamin A per gram.

It was alleged to be misbranded in that the statements, "In place of each 4¾ lbs. straight 85–D Oil use 1 lb. Sea–Clo–400–D. In place of each 1 lb. Fortified 400–D Oil use 1 lb. Sea–Clo–400–D. For each 5 pints 85–D Oil used, replace with 1 lb. Sea–Clo–400–D," and "Guaranteed to contain 400 A. O. A. C. units of Vitamin D. per gram. When this product is packed it contains more than 1,000 units of Vitamin 'A' per gram, but due to a difference of opinion of our many authorities regarding the stability of Vitamin 'A' from Cod Liver Oil when added to feeds, we are making no claim for it," appearing in the labeling, were false and misleading since it contained less than 400 units of vitamin D per gram and contained materially less than 1,000 units of vitamin A per gram, and 1 pound of the article would not be equivalent in feeding value or as a source of vitamin D and vitamin A to 4¾ pounds of straight 85–D cod liver oil, or 1 pound of fortified 400–D cod liver oil or 5 pints of 85–D cod liver oil.

The article was also charged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2645.

On March 24, 1941, the defendant having entered a plea of nolo contendere, the court imposed a fine of $150.

482. Adulteration and misbranding of sardine oil. U. S. v. Industrial Oil Products Corporation. Plea of nolo contendere. Fine, $100 on count I. Imposition of of sentence suspended on remaining counts. (F. D. C. No. 4155. Sample Nos. 24504-E, 40103-E.)

This veterinary product contained less vitamin D than the amount declared on the label.

On August 7, 1941, the United States attorney for the Southern District of California filed an information against the Industrial Oil Products Corporation, trading at Los Angeles, Calif., alleging shipment on or about September 4 and October 24, 1940, from the State of California into the State of New Jersey of quantities of sardine oil which was adulterated and misbranded. The article was labeled in part: "Fox Special Sardine Oil * * * The Fox Company, Newfield, New Jersey."

It was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported or was represented to possess since it was represented in its labeling to contain 85 A. O. A. C. chick units of vitamin D per gram; whereas it contained less than so represented, the product in one shipment containing not more than 60 and that in the other shipment containing not more than 65 A. O. A. C. chick units of vitamin D per gram.

It was alleged to be misbranded in that the statement "Guaranteed 85 AOAC Chick Units of Vitamin D per Gram," borne on the drum, was false and misleading since the article contained less than 85 A. O. A. C. chick units of vitamin D per gram.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2648.

On August 28, 1941, a plea of nolo contendere having been entered, the court sentenced the defendant to pay a fine of $100 on count I and suspended imposition of sentence on the remaining 7 counts.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING STATEMENTS IN THE LABELING[3]

Nos. 483 to 536, inclusive, report actions based on interstate shipment of drugs or devices the labeling of which contained false and misleading statements—in most instances regarding their therapeutic efficacy.

483. Misbranding of El Panal Cuban Honey. U. S. v. Albert H. Hoffman (Hoffman Health Products Co.). Plea of guilty. Fine, $50. (F. D. C. No. 960. Sample No. 65858-E.)

This honey was falsely labeled to indicate that it possessed minerals and other nutritional elements materially in excess of those contained in ordinary honey. Its label also bore false and misleading representations regarding its efficacy in the conditions indicated below.

On May 28, 1940, the United States attorney for the Southern District of Florida filed an information against Albert H. Hoffman, trading as Hoffman Health Products Co., Tampa, Fla., alleging shipment on or about October 14, 1939, from the State of Florida into the State of North Carolina, of a quantity of El Panal Wonder Honey that was misbranded. The article was labeled in part: "El Panal Cuban Honey. Imported direct from Cuba."

The article was alleged to be misbranded in that certain statements in the labeling were false and misleading since they represented and implied that it was a "Wonder Honey," i. e., that it differed materially from ordinary honey; and that it contained minerals which help build nerve, bone, and muscle tissue materially in excess of those contained in ordinary honey; that it would supply the elements valuable in ailments resulting from mineral deficiencies in amounts materially in excess of such minerals found in ordinary honey; that it possessed proportionately high amounts of potassium, sodium, calcium, magnesium, iron, phosphorus, chlorine, sulfur, silicon, and undetermined minerals; that it possessed value as a food, body builder, and constructive nutritional factor materially in excess of that possessed by ordinary honey; and that it contained minerals and other nutritional elements lacking in other honey;

[3] See also Nos. 426, 427, 429, 431–434, 436–448, 451–454, 459, 460, 468, 470, and 471.

whereas it did not differ materially from ordinary honey. It was alleged to be misbranded further in that certain statements in the labeling were false and misleading since they represented that it possessed efficacy as a dietary supplement in the treatment of sinus, coughs, asthma, hay fever, constipation, stomach ulcers, digestive ailments; that it possessed efficacy as a general tonic and body builder and had produced effective results in the treatment of such ailments; that it possessed natural healing properties; that it was of great value to both children and adults who are anemic, have poor appetite and other symptoms of rundown condition; that it would alkalize, vitalize, and upbuild the body; that it would aid in preventing respiratory ailments and would build resistance; that it was efficacious to produce improvement in general health of children; that it was efficacious in relieving the attacks of asthma, coughs, and bronchitis; would help remove mucus and was a boon to raw and inflamed respiratory tracts; that it was efficacious in relieving pain, reducing inflammation and healing the ulcerous surfaces in ulcers of the stomach; that it was efficacious in bowel and colon trouble by helping to change the intestinal flora, and that its lubricating effect would aid in relieving pain and discomfort and assist nature to overcome the ailment; that it was an accessory of great value in many disease conditions; that it was beneficial for asthma and kindred disorders; that it contained a pollen which would counteract the pollen which causes hay fever; that it was highly beneficial for stomach disorders such as ulcers, and for combating constipation; that it was efficacious for various pathogenic conditions of the body; that its healing properties were without equal; that it was efficacious to relieve bronchial asthma and sinus condition and to prevent choking sensation of asthma and to induce restful sleep; that it was efficacious to heal ulcerated stomach; that it was efficacious as a tonic and body builder and would induce increase in weight; that it was efficacious in the treatment of rundown conditions; highly mucous condition of the throat and chest, and enlarged tonsils; that it would promote sound restful sleep and build health, and that it had accomplished wonderful results in the aforesaid conditions; whereas it would not be efficacious for such purposes.

On July 18, 1941, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of $50.

484. Misbranding of Diabet Tea. U. S. v. Paul Constantini, Angelo Constantini, and Anselmo Constantini (Diabet Tea Co.). Case tried to a jury. Verdict of guilty. Fines, $150. Defendants all placed on probation for three years. (F. D. C. No. 2969. Sample No. 34721–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the treatment of diabetes.

On May 16, 1941, the United States attorney for the Middle District of Pennsylvania filed an information against Paul Constantini, Angelo Constantini, and Anselmo Constantini, copartners trading as Diabet Tea Co. at Scranton, Pa., alleging shipment by said defendants on or about September 9, 1940, from the State of Pennsylvania into the State of New York of a quantity of Diabet Tea that was misbranded.

Analysis of a sample of the article showed that it consisted of the ground herb *Hypericum perforatum*, commonly known as St. Johnswort.

The article was alleged to be misbranded in that the statements on the label, "Nature's Food Diabet-Tea for Diabetes. The contents of this package has been carefully prepared for the use of those who suffer from diabetes," were false and misleading since they represented that it was for the cure, mitigation, treatment, or prevention of diabetes; whereas it was worthless for such purposes.

On November 5, 1941, the case was tried before a jury, which returned a verdict of guilty, and the defendants were each fined $50. Imposition of jail sentences was suspended and the defendants were placed on probation for 3 years.

485. Misbranding of Kurex Diabetic Tonic. U. S. v. Kurex Hillgrove Laboratories, Inc., Richard F. Hillgrove, and Walter P. Weihe. Pleas of nolo contendere. Corporation fined $250. Richard F. Hillgrove and Walter P. Weihe fined $250 but payment ordered suspended. (F. D. C. No. 2935. Sample No. 27071–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter and failed to declare the common or usual name of each active ingredient.

On March 19, 1941, the United States attorney for the Southern District of Ohio filed an information against the Kurex Hillgrove Laboratories, Inc., Cincinnati,

Ohio, Richard F. Hillgrove, and Walter P. Weihe, alleging shipment on or about September 26, 1940, from the State of Ohio into the State of West Virginia of a quantity of Kurex Diabetic Tonic which was misbranded.

Analysis showed that the article consisted chiefly of water, alcohol, reducing sugars, and plant extractives including emodin-bearing drugs and a trace of unidentified alkaloids.

The article was alleged to be misbranded in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient, including the kind, quantity, and proportion of alcohol. It was alleged to be misbranded further in that representations in the labeling that it would be efficacious in the treatment of diabetes; would enable the diabetic patient to eliminate the taking of insulin; was efficacious in the treatment of blindness caused by diabetes; would heal feet which were open as the result of diabetes; would heal legs which were ulcerated as the result of diabetes; would be efficacious in the treatment of run-down conditions and other ailments contracted by poor living conditions; was a systemic tonic and would be efficacious in the treatment of many ailments common to bad blood and other conditions such as rheumatism and ailments caused by kidney disorders; and would restore lost appetite and improve the nervous condition and general health.

On May 26, 1941, pleas of nolo contendere were entered on behalf of all defendants. The court imposed a fine of $250 against each of the defendants but ordered that payment of the fines of the individual defendants Richard F. Hillgrove and Walter P. Weihe be suspended.

486. Misbranding of Dickson's Herb-Lax Tonic. U. S. v. Addison H. Dickson (A. H. Dickson). Plea of guilty. Fine, $100. (F. D. C. No. 2837. Sample No. 9583-E.)

This product was falsely labeled to imply that it was a laxative compound composed entirely of, and deriving its laxative properties solely from, herbs. Furthermore, it bore false and misleading representations regarding its efficacy as a tonic and in the treatment of certain diseases.

On October 8, 1940, the United States attorney for the Western District of Tennessee filed an information against Addison H. Dickson, trading as A. H. Dickson, at Memphis, Tenn., alleging shipment on or about May 3, 1940, from the State of Tennessee into the State of Louisiana, of a quantity of Dickson's Herb-Lax Tonic that was misbranded.

Analysis of a sample of the article showed that it consisted essentially of Epsom salt (approximately 28 grams per 100 cc.), small proportions of methenamine, salicylic acid, sodium benzoate, plant extracts including nux vomica, and a resinous substance such as podophyllum, a trace of iron, and water flavored with peppermint oil.

This drug was alleged to be misbranded in that its name or designation "Herb-Lax Tonic," borne on the bottle label, was false and misleading since it represented that the drug was a laxative compound composed entirely of herbs and that it derived its laxative properties solely from herbs; whereas it was not a laxative compound composed entirely of herbs but did consist in part of Epsom salt, a mineral substance; and it did not derive its laxative properties solely from herbs but did derive its laxative properties in large part from Epsom salt. It was alleged to be misbranded further in that the following statements "Herb-Lax Tonic * * * Recommended for Indigestion * * * Biliousness, Nervousness, Bad Blood, Rheumatism, Urinary Troubles and General Rundown Conditions," borne on the bottle label, were false and misleading since it was not efficacious for such purposes.

On October 31, 1940, the defendant entered a plea of guilty and the court imposed a fine of $100.

487. Misbranding of Locao Belem. U. S. v. Belem Products Co. Plea of guilty. Fine, $75. (F. D. C. No. 2968. Sample Nos. 32807-E, 32808-E.)

On September 11, 1941, the United States attorney for the Southern District of Texas filed an information against Belem Products Co., a corporation, Houston, Tex., alleging shipment on or about November 1, 1940, from the State of Texas into the State of California of a number of 3-ounce and 6-ounce bottles of Locao Belem that was misbranded.

Analysis of a sample of the article showed that it consisted chiefly of water, alcohol, a foam producer, a small amount of glycerin, and perfume materials.

The article was alleged to be misbranded in that statements in the labeling representing that it was efficacious in the treatment of baldness, falling hair,

dandruff, and irritated scalp; that ordinarily dandruff or itching scalp would respond quickly to treatment with it and that satisfactory improvement or even complete elimination of these conditions would result in from 2 to 4 weeks; that it would bring about improvement in the less severe cases of falling hair in a few weeks and would be efficacious to correct the more severe cases of falling hair in from 3 to 6 months; and that it would be efficacious to develop new growth on bald areas, were false and misleading since it would not be efficacious for such purposes. The article in the 3-ounce bottles was alleged to be misbranded further in that the statement "Locao Belem has been thoroughly analyzed by the Pure Food and Drugs Department of the United States Customs and complies with rigid requirements of Pure Food and Drug Laws," appearing on the cartons, was false and misleading since it had not been found by a Government agency to be in strict compliance with the requirements relating to foods and drugs and it did not comply with the Federal Food, Drug, and Cosmetic Act.

On September 25, 1941, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of $75.

488. Misbranding of Neff's Glan-Tex Tonic. U. S. v. George G. Neff (Prostex Co.). Plea of nolo contendere. Judgment of guilty. Fine, $250 and costs. (F. D. C. No. 2883. Sample Nos. 16614–E, 16622–E.)

On March 22, 1941, the United States attorney for the Northern District of Oklahoma filed an information against George G. Neff, trading as the Prostex Co., Miami, Okla., alleging shipment on or about March 22 and April 1, 1940, from the State of Oklahoma into the State of Missouri, of quantities of Neff's Glan-Tex Tonic which was misbranded. The article was labeled in part: "Neff's Glan-Tex Tonic * * * Prostex Co. Miami, Okla."

Analysis showed that it consisted essentially of magnesium sulfate, small proportions of ammonium alum, a mineral acid such as sulfuric acid, minute proportions of quinine, compounds of potassium and iron, and a nitrate in water.

The article was alleged to be misbranded in that the name "Glan-Tex-Tonic," the word "Prostex" in the firm name, which appeared in the labeling, and certain statements in an accompanying circular were false and misleading since they represented that it was a gland tonic; that it would be efficacious in the treatment of prostate gland cases and kindred ailments of kidneys, bladder and urinary tract, colitis, dropsy, rheumatism, and infected internal organs; that it would be efficacious in the treatment of acute cases of suffering from prostatitis, irritated bladder disorders, and kindred ailments; that it would be beneficial in kidney disorders and dropsy, and would reduce the prostate gland and eliminate infection; that it would reduce enlarged glands, inflammation and swollen prostate glands in most cases; that it would be efficacious for the relief of pains and discomfort caused by prostatitis, cystitis (bladder trouble), urethritis, difficulty in urination, dribbling, getting up nights, congested and irritated condition of the prostate gland and urinary tract; that it would be efficacious for the relief of rheumatism, neuralgia, and pain occasioned by acute or chronic irritation and congestion; that it would be valuable as an antiseptic; and that it contained internal antiseptics; whereas it was not a gland tonic and it would not be efficacious for the purposes for which it was so recommended.

On December 8, 1941, a plea of nolo contendere having been entered, the court found the defendant guilty and imposed a fine of $250 on count I of the information, together with costs, and placed the defendant on probation for 1 year on count II.

489. Misbranding of No-Wheez Cough Syrup and No-Wheez for Asthma. U. S. v. No-Wheez Corporation. Plea of guilty. Fine, $101. (F. D. C. No. 2878. Sample Nos. 15413–E, 15414–E.)

On January 30, 1941, the United States attorney for the Eastern District of Missouri filed an information against the No-Wheez Corporation, St. Charles, Mo., alleging shipment on or about March 1 and May 24, 1940, from the State of Missouri into the State of Illinois of quantities of No-Wheez Cough Syrup and No-Wheez for Asthma, which were misbranded.

Analyses of samples of the articles showed that the No-Wheez Cough Syrup consisted essentially of small proportions of pine tar, menthol, an emodin-bearing drug, chloroform, sugar, and water; and that the No-Wheez for Asthma consisted essentially of small proportions of inorganic salts commonly found in mineral water, pine tar, and an emodin-bearing drug, and water.

The articles were alleged to be misbranded in that representations in the labeling (No-Wheez Cough Syrup) that it would be efficacious in the treatment

of bronchitis, whooping cough, sore throat, and other such irritations, and that it would prevent wheezing in said disorders; and (No-Wheez for Asthma) that it would be efficacious in the treatment of asthma and hay fever, that it would bring lasting relief to asthma and hay fever sufferers, and that it would prevent wheezing in asthma and hay fever, were false and misleading since they would not be efficacious for such purposes.

On May 6, 1941, a plea of guilty having been entered on behalf of the company, the court imposed a fine of $101.

490. Misbranding of Pedimoll. U. S. v. Pedimoll Corporation. Plea of nolo contendere. Fine, $100. (F. D. C. No. 2881. Sample Nos. 7444-E, 7445-E.)

On January 17, 1941, the United States attorney for the Southern District of California filed an information against the Pedimoll Corporation, Los Angeles, Calif., alleging delivery on or about April 25, 1940, for introduction in interstate commerce from the State of California into the State of New York of a quantity of Pedimoll that was misbranded. It was labeled in part: "Pedimoll * * * A Creme for the Feet."

Analysis of a sample of the article showed that it consisted essentially of a magnesium compound and small proportions of sulfur and cresol in an oil base.

The article was alleged to be misbranded in that statements in the labeling representing that it would be efficacious in the treatment of bunions, callouses, corns, tired, aching, sore, swollen or sweaty feet, muscular soreness, most skin irritations, eczema, acne; that it would be efficacious for the elimination of athlete's foot, impetigo, sunburn; that the daily use of the drug would prevent suffering with one's feet, defeat foot troubles, and make walking a pleasure; that it was efficacious as a remedy for tired, sore, swollen, cracked, blistered, burning, itching, irritated, infected, aching or painful feet; that it would have a swift germicidal effect and a safe healing action; that said drug would almost instantly relieve the burning and soreness, reduce the swelling, stimulate circulation and normalize tired feet; that it would relieve the soreness and reduce the swelling and inflammation of corns, callouses and bunions, and would cause callouses and corns to soften and gradually disappear; that when used on any part of the body, it would relieve conditions caused by muscular soreness and strain, swelling, itching, sunburn, bruises, insect bites, sore joints, varicose veins, eczema, acne, impetigo, chapped hands; that children, by its use, would be spared suffering from corns and callouses, and infections which often mean a sacrifice to the general health of the growing child; that it would prevent infection if applied to the feet immediately before or after exposure; that it would penetrate and act as a safeguard covering against athlete's foot; that it would reach deep into the pores and purge the skin of impurities; that it would restore the normal elimination through the pores of the feet and correct excessive perspiration or extreme dryness, and would give almost instant relief in most forms of foot trouble; that a small quantity of said drug, rubbed into the feet until it disappeared, would enable the user to walk over the worst infected floors of clubs, gymnasiums or swimming pools without fear of most infections, and that a daily treatment would prevent reinfection from shoes and other sources; that it would keep the feet of businessmen fit and would keep the feet of salespeople in the best of condition; that it would help nature reestablish surface skin; that it would be efficacious in the treatment of nervous, wobbly, stiff, swollen, flabby, knotty legs, and varicose veins; would tone the circulation, soothe the nerves, loosen the knotted adhesions within the muscles, relieve soreness and swelling, promote healing, and foster elasticity of hardening vein walls, and would enliven the legs and give them pep and endurance; that its use would be beneficial and relieving after removing surgical stocking or bandages from a leg or ankle which has suffered a strain or break or varicose vein condition; and that its use would keep legs which are limber and graceful in such condition, were false and misleading since it would not be efficacious for such purposes.

On February 17, 1941, a plea of nolo contendere was entered on behalf of the defendant and the court imposed a fine of $100.

491. Misbranding of Robinson's for Rheumatism, Arthritis, Neuritis, and Lumbago. U. S. v. Albert J. Robinson. Plea of nolo contendere. Judgment of guilty. Fine, $25. (F. D. C. No. 2856. Sample No. 1883-E.)

On November 18, 1940, the United States attorney for the Eastern District of Pennsylvania filed an information against Albert J. Robinson, Allentown, Pa., alleging shipment on or about May 29, 1940, from the State of Pennsylvania into

the State of Maryland of a quantity of the above-named product which was misbranded.

Analysis of a sample of the article showed that it consisted essentially of potassium iodide (44.8 grams per 100 cc.) and alcohol (5 percent).

The article was alleged to be misbranded in that the statements, (bottle label) "For Rheumatism, Arthritis, Neuritis, Lumbago * * * A Foe to Pain," and statements in an accompanying circular representing that it was efficacious in the treatment of rheumatism, arthritis, neuritis, sciatica, and lumbago; that it would heal, would restore to normalcy helpless victims of rheumatism, arthritis, neuritis, sciatica, and lumbago; that it would restore to health, would bring freedom from pain and distress, and would bring perfect health regardless of whether the condition was of recent origin or had developed to a serious stage; and that it would relieve suffering and disability, were false and misleading since it was not efficacious for such purposes.

On December 5, 1940, the defendant entered a plea of nolo contendere, was adjudged guilty, and a fine of $25 was imposed.

492. Misbranding of Vitalex Perdiz. U. S. v. Manuel Perdiz (Vitalex Laboratories). Plea of guilty. Fine, $100. (F. D. C. No. 2986. Sample No. 4576–E.)

The labeling of this product not only contained false and misleading statements regarding its therapeutic qualities, its vitamin B_1 content, and the absence of any injurious drugs, but the glass vial containing the tablets occupied only about one-half of the capacity of the carton in which they were packed.

On July 23, 1941, the United States attorney for the Western District of New York filed an information against Manuel Perdiz, trading as Vitalex Laboratories at Buffalo, N. Y., alleging shipment on or about May 16, 1940, from the State of New York into the State of Indiana of a quantity of Vitalex Perdiz which was misbranded.

Analysis of a sample of the article showed that it contained glycerophosphates of sodium and calcium, small proportions of iron phosphate, zinc phosphide, and nux vomica, and indications of brewers' yeast and extract of cod-liver oil, coated with calcium carbonate and colored pink. Biological examination showed that it contained approximately 5 International Units of vitamin B_1 per tablet.

The article was alleged to be misbranded: (1) In that the following statements (bottle label and wrapper, English) "Recommended for Tiredness, Loss of Weight, Irritability and Nervousness, Lack of Appetite, Lack of Energy and Pale Complexion when due to Nutritional Anemia or Secondary Anemia," and (translation from Spanish) "It is recommended for Fatigue, Loss of Weight, Irritability and Nervousness, Lack of Appetite, Lack of Energy and Pallor of the Face and Anemia caused by nutritional deficiency," were false and misleading since it would not be efficacious for such purposes. (2) In that representations in the labeling, i. e., the name "Vitalex" and the statement (wrapper) "This exceptional Tonic is made of fine ingredients of recognized medicinal value combined with vitamins B," and (wrapper and bottle label) "Active ingredients * * * vitamin * * * B * * * Dose 4 tablets a day," were false and misleading since they represented and suggested that the drug contained a therapeutic amount of vitamin B_1, whereas it contained an amount of B_1 which would be inconsequential for therapeutic purposes; and its labeling failed to reveal the fact, material in the light of such representations, that the total daily dosage recommended, i. e., 4 tablets, would supply less than one-thirtieth of the average therapeutic dose of vitamin B_1. (3) In that the statement (wrapper), "It does not contain any injurious * * * drugs," was false and misleading since it contained nux vomica and zinc phosphide, drugs which might be injurious. (4) In that its containers (cartons) were so made, formed, and filled as to be misleading.

On December 15, 1941, the defendant entered a plea of guilty and the court imposed a fine of $100.

493. Misbranding of Dr. Shreve's Anti-Gall-Stone Remedy. U. S. v. 8 Packages of Dr. Shreve's Anti-Gall-Stone Remedy. Default decree of condemnation and destruction. (F. D. C. No. 3161. Sample No. 30909–E.)

This preparation consisted of a bottle of liquid and an envelope containing pills labeled "Dr. Shreve's S and L Pills."

On October 23, 1940, the United States attorney for the Northern District of Indiana filed a libel against 8 packages of Dr. Shreve's Anti-Gall-Stone

Remedy at Michigan City, Ind., alleging that the article had been shipped on or about May 11, 1940, by Dr. Shreve's Medicine Co. from Newton, Iowa; and charging that it was misbranded.

Analysis of a sample of the article showed that the liquid consisted essentially of limewater containing a white sediment and flavored with sassafras; and that the pills contained plant material (including a laxative plant drug) and metallic mercury (equivalent to 0.68 grain of mercury with chalk per pill), and were coated with sugar and calcium carbonate.

The Anti-Gall-Stone Remedy was alleged to be misbranded in that the following statements on the wrapper and bottle label, "Anti-Gall-Stone Remedy," and statements in an accompanying circular representing that it would be efficacious as a gall-stone remedy; that it would produce a chemical change in the gall and would alter the secretions of the gall bladder, liver, kidneys, and bladder; and that it would place the system in a better condition, were false and misleading since it would not be efficacious for such purposes.

Dr. Shreve's S and L Pills were alleged to be misbranded in that statements in the labeling representing that they would be efficacious as a treatment for catarrh of the stomach or bowels, dizziness, nausea, diarrhea or dysentery; that they would promote digestion and assimilation and would restore tone to the system; and that they would be efficacious as a laxative for biliousness and sour stomach, were false and misleading since they would not be efficacious for such purposes.

On December 3, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

494. Misbranding of A-Z Tablets. U. S. v. 214,900 A-Z Tablets. Consent decree of condemnation and destruction. (F. D. C. No. 3089. Sample No. 33388-E.)

On September 26, 1940, the United States attorney for the District of Connecticut filed a libel against 214,900 drug tablets at Waterbury, Conn., alleging that the article had been shipped in interstate commerce by Strong, Cobb & Co., Inc., from Cleveland, Ohio, on or about June 8, 1940. These tablets were shipped in bulk; subsequently they were repacked and labeled in part: "A-Z Tablets * * * Distributed by A-Z Sales Company Waterbury, Conn."

Analysis of a sample of the article showed that it consisted essentially of potassium acid tartrate, calcium gluconate, sulfur, podophyllum, goldenseal, starch, and a small amount of an iron compound.

The libel alleged that the article so labeled was misbranded in that statements on the box label and in an accompanying circular representing that it would be efficacious in the treatment of asthma, asthmatic spasms, bronchitis, bronchial irritations, catarrh, congestion of the upper respiratory system, hay fever, head colds, and nasal irritations, were false and misleading since it would not be efficacious for such purposes.

On April 8, 1941, Phillips & Benjamin Co., Waterbury, Conn., and Strong, Cobb & Co., Inc., claimants, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

495. Misbranding of Colloidal Dextro Calcium. U. S. v. 110 Bottles of Colloidal Dextro Calcium Bleything. Default decree of condemnation and destruction. (F. D. C. No. 3358. Sample No. 44102-E.)

This product did not contain the amount of calcium suggested and indicated in its labeling but did contain sodium benzoate materially in excess of the amount declared.

On November 12, 1940, the United States attorney for the District of Colorado filed a libel against 110 bottles of the above-named product at Denver, Colo., which had been shipped by the Bleything Laboratories, alleging that the article had been shipped in interstate commerce on or about October 17, 1940, from Los Angeles, Calif.; and charging that it was misbranded.

The article was alleged to be misbranded in that the statements on the label, "Colloidal Dextro Calcium Bleything * * * Dosage: One teaspoonful three times daily before meals. May be taken in milk or fruit juices, if preferred. In pronounced cases dosage may be doubled for two weeks. Dosage for children is the same as for adults," were false and misleading since they created the impression that it would supply the consumer with a significant amount of calcium even in pronounced cases of calcium deficiency when used as directed, when, in fact, it would supply but a negligible amount of calcium. The article was alleged to be misbranded further in that the statement on the label, "Less than 1/20 of

1% Sodium Benzoate," was false and misleading since it contained materially more than 1/20 of 1 percent of sodium benzoate.

The article was also alleged to be misbranded under the provisions of law applicable to foods, as reported in F. N. J. No. 2098.

On November 26, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

496. Misbranding of Enrich. U. S. v. 30 Bottles of Enrich. Default decree of condemnation and destruction. (F. D. C. No. 3706. Sample No. 99914–E.)

On January 24, 1941, the United States attorney for the District of Columbia filed a libel against 30 bottles of Enrich, alleging that it was being offered for sale in the District of Columbia at the Vita Health Food Co., Washington, D. C.; and charging that it was misbranded. It was labeled in part: "Each fluid-oz. contains 600 mg. Peptonized Iron, 200 U. S. P. units Vitamin B_1, 100 micrograms Vitamin B_2 (riboflavin), Rice Bran Extract (which contributes other factors of the Vitamin B complex), Manganese as the citrate, Calcium and Sodium as the glycerophosphates. * * * Two teaspoons of Enrich 4 times daily furnish 99 milligrams of iron. * * * Two teaspoons of Enrich 4 times daily, supply four-fifths, 80%, of the entire day's needs (minimum U. S. standard)."

It was alleged to be misbranded in that the following statements appearing on a placard accompanying it were false and misleading since it was not efficacious for the purposes recommended: "New Hope For Folks Over 40. This combination of iron and vitamin B_1 has helped to restore pep and vigor to thousands. If you suffer from low vitality, neuritis, nervousness, or other nerve disorders, stomach distress, colitis, or constipation, loss of appetite, pale cheeks, lips, eyelids, or gums, poor functioning, iron-poor blood, cold hands or feet, loss of vigor, you may need more of the vital elements iron and vitamin B_1. Enrich benefits your blood, nerves, glands, and every organ of your body if you lack iron and vitamin B_1."

On February 26, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

497. Misbranding of gelatin. U. S. v. 203 Cases of Gelatin. Consent decree of condemnation. Product ordered released under bond for relabeling. (F. D. C. No. 4693. Sample Nos. 40349–E, 40350–E.)

The labeling of this product bore false and misleading representations concerning its value for avoiding and reducing fatigue and increasing energy and endurance.

On May 8, 1941, the United States attorney for the District of New Jersey filed a libel against 203 cases of gelatin at Camden, N. J., alleging that the article had been shipped in interstate commerce on or about March 20 and April 16, 1941, by Charles B. Knox Gelatine Co., Inc., from Johnstown, N. Y.; and charging that it was misbranded.

The article was alleged to be misbranded in that the following designs, devices, and statements appearing in the circular accompanying both shipments and further and similar statements, designs, and devices in a booklet accompanying one of the shipments, concerning the value of the product for avoiding fatigue and increasing energy and endurance, were false and misleading: "How Knox Gelatine Works For You! * * * For Endurance [vignette of pamphlet entitled "Fatigue And the New Way to Avoid It" and portraying pictures of individuals engaged in various physical activities] * * * The New Use For Knox Gelatine * * * The Knox Gelatine diet is being adopted by men and women all over the country who report that it really works. Hundreds of people who have completed 28-day occupational group tests have reported that Knox Gelatine has reduced fatigue to a significant degree. This is not theory. It is based upon carefully collected reports of men and women whose work makes strenuous demands on mental and physical endurance. If you could use more endurance, try the Knox Gelatine endurance diet, yourself. Have members of your family try it. * * * Ask people to try Knox Gelatine for greater endurance * * *. How to Take Knox Gelatine For More Endurance—Less Fatigue * * * Stock the new 32-envelope economy package and make the Knox Endurance Routine easy for your customers. * * * Answering Your Customers Question About Knox Gelatine * * * The latest research development—and the most wide-spread—is the use of Knox Gelatine in building endurance and resistance to fatigue. Booklets on Knox Gelatine for greater endurance * * * are available on request."

The article was also alleged to be misbranded in violation of the provisions of the law applicable to foods reported in F. N. J. No. 2548.

On August 15, 1941, the Charles B. Knox Gelatine Co., Inc., having appeared as claimant and having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond conditioned that the circulars and booklets be removed from the packages under the supervision of the Food and Drug Administration.

498. Misbranding of Wiel Garlic Tablets. U. S. v. 174 Tins, 88 Bottles, and 500 Envelopes of Wiel Garlic Tablets. Default decree of condemnation and destruction. (F. D. C. No. 3005. Sample Nos. 33458-E, 33459-E.)

On September 17, 1940, the United States attorney for the District of New Jersey filed a libel against the following amounts of Wiel Garlic Tablets at Newark, N. J.—174 tins each containing 24 tablets, 88 bottles each containing 120 tablets, and 500 envelopes each containing 4 tablets, alleging that the article had been shipped by Wiel Laboratories, Inc., from Brooklyn, N. Y., on or about March 2, 1940; and charging that it was misbranded.

Analysis of a sample of the article showed that the tablets contained a small amount of garlic coated with sugar, calcium carbonate, and a starchy material, flavored with peppermint.

The article was alleged to be misbranded in that certain statements appearing in the labeling were false and misleading since they represented that it would build better health, stimulate digestion, and reduce high blood pressure; that garlic causes the relaxation and expansion of the tiny blood vessels and small arteries, which have the direct and immediate effect of lowering blood pressure; that it would act by stimulating peristaltic movement of the bowels, and would aid in dispelling excessive flatulent gas and its disagreeable symptoms of nervous fatigue, coated tongue, and sleeplessness; and that it would relieve that peculiar dizziness and headache which usually accompanies high blood pressure, and would help to overcome jumpy nerves due to ordinary constipation; whereas it would not be efficacious for such purposes.

On January 31, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

499. Misbranding of honey. U. S. v. 36 Packages and 75 Packages of Honey. Default decrees of condemnation. Portion of product ordered destroyed; remainder ordered delivered to a charitable institution. (F. D. C. Nos. 3977, 3980. Sample Nos. 44027-E, 44640-E.)

On March 15, 1941, the United States attorney for the Middle District of Tennessee filed a libel against 36 packages of honey at Dickson, Tenn., alleging that the article had been shipped in interstate commerce on or about February 5, 1941, by the Tongue River Apiaries (E. C. Reed & Son) from Ranchester, Wyo. On March 31, 1941, the United States attorney for the District of Colorado filed libel against 75 packages of honey at Denver, Colo., which had been shipped by Tongue River Apiaries on or about October 1, 1940, from Ranchester, Wyo.

The article was alleged to be misbranded in that the statements on the carton, "Health Sweet," "Helpful for impaired digestion, diabetes, etc.," and "A teaspoonful in warm water induces sleep and stimulates the heart," were false and misleading since the use of the article could not be depended upon to fulfill the promises of benefit stated and implied thereby. It was alleged to be misbranded further in that statements in an accompanying circular entitled "Please Pass the Honey," regarding its efficacy in the maintenance of health, its efficacy in the treatment of heart weakness and heart failure and in reviving heart action, its efficacy in the treatment of pneumonia and its value for general physical repair, its efficacy to produce energy and give the user a healthy complexion, and its efficacy as a cosmetic because of its nourishing, bleaching, astringent, and antiseptic effect on the skin, were false and misleading since it would not be efficacious for such purposes. It was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2813.

On May 27 and on June 28, 1941, no claimant having appeared, judgments of condemnation were entered and the product seized at Denver was ordered delivered to a charitable institution and that seized at Dickson was ordered destroyed.

500. Misbranding of Dr. Carey's Marsh Root Prescription 777 Tablets (and Laxative Pills). U. S. v. 105 Packages of Dr. Carey's Marsh Root Prescription 777 Tablets. Default decree of condemnation and destruction. (F. D. C. No. 3134. Sample No. 1391–E.)

On or about October 7, 1940, the United States attorney for the Western District of Virginia filed a libel against 105 packages of the above-named products at Roanoke, Va., which had been consigned by the Earle Soap Manufacturing Co., alleging that the article had been shipped from Baltimore, Md., on or about September 13, 1940; and charging that it was misbranded. Accompanying each bottle of this product was an envelope that contained 4 pills labeled "Dr. Carey's Marsh Root Laxative Pills."

Analyses of samples showed that the Prescription 777 Tablets consisted essentially of plant drugs including a laxative drug and an alkaloid-bearing drug, methyl salicylate, sodium salicylate, potassium nitrate, sugar, starch, and talc; and that the Laxative Pills consisted essentially of plant material, including a laxative drug.

The packages of Marsh Root Prescription 777 Tablets were alleged to be misbranded in that the names "Dr. Carey's Marsh Root Prescription 777 Tablets" and "Dr. Carey's Marsh Root Laxative Pills" were false and misleading since the tablets and the pills both contained therapeutically active ingredients other than marsh root. They were alleged to be misbranded further in that statements appearing upon and within the package representing that Prescription 777 Tablets would be efficacious as a diuretic, as a stimulant of the kidneys and urinary system, and as a cure, preventive, or mitigation of kidney diseases; and that the Laxative Pills would be efficacious as a tonic, that they were "gentle as Nature," that they were not habit-forming, that they were of value for sufferers of kidney or bladder troubles, and that it is necessary for an individual to have laxation before any medication is effective, were false and misleading since the tablets and the pills would not be efficacious for such purposes.

On January 14, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

501. Misbranding of Myasthene Tablets. U. S. v. 183 Bottles of Myasthene Tablets (and 1 other seizure action against Myasthene Tablets). Default decrees of condemnation and destruction. (F. D. C. Nos. 2483, 2643. Sample Nos. 1676–E, 1677–E, 1678–E, 28932–E.)

On August 2 and 21, 1940, the United States attorney for the District of Columbia filed libels against 326 bottles of Myasthene Tablets at Washington, D. C., alleging that 183 of said bottles had been shipped in interstate commerce on or about March 30, 1940, by the Medicinal Specialties Co. from New York, N. Y., and that 143 were being offered for sale in the District of Columbia at various branches of the Whelan Drug Co., Inc.; and charging that the article was misbranded.

Analysis showed that it contained 7.5 grains of aminoacetic acid (glycocoll) per tablet.

It was alleged to be misbranded in that representations in the labeling that it would increase the chemical source of muscular energy, would increase muscle phosphocreatine in the system when a deficiency existed, would provide energy for muscle action, would relieve tiredness or fatigue, would be efficacious in the treatment of muscular ailments, including mild muscular debility; and in that representations in the labeling of a portion of the article that it would check tiredness, pep up muscles, and give the user an amazing feeling of strength, that it would relieve weakness, exhaustion, run-down conditions, and lack of pep and appetite, that it would produce amazing results in conditions of overwork and of protein deficiency, would increase the chemical source of energy for muscular action right in the muscles themselves, that it would combat certain poisonous substances which ordinarily may be harmful, and would give the user vim, vigor, pep, and energy, were false and misleading, since it would not be efficacious for such purposes.

On March 14, 1941, the claim and answer of the Medicinal Specialties Co. having been withdrawn, judgments of condemnation were entered and the product was ordered delivered to the Food and Drug Administration for technical uses.

502. Misbranding of Regol. U. S. v. 8 Bottles, 20 Bottles, and 35 Bottles of Regol. Consent decree of condemnation and destruction. (F. D. C. No. 3605. Sample No. 31529–E.)

On December 30, 1940, the United States attorney for the Eastern District of Michigan filed a libel against 63 bottles of Regol at Detroit, Mich., alleging that

the article had been shipped by the Cleveland Von Co. from Cleveland, Ohio, on or about November 26, 1940; and charging that it was misbranded.

Analysis showed that the article consisted of a preparation of bile and extracts of plant drugs dissolved in alcohol (26 percent), and water.

The article was alleged to be misbranded: (1) In that statements in circulars entitled "Regol A Liver Medicine," representing that it was a rational and effective remedy for diseases of the liver, digestive disorders, fermentation and gas in the intestines, intestinal indigestion, sick headache, chronic constipation, chronic inflammation in the walls of the colon, commonly called colitis, catarrhal irritation of the intestines, disturbance of the bile secreting function of the liver, disease of the gall bladder and gall ducts, gall-bladder congestion, discomfort from the gall bladder, faulty flow of bile, belching, sour eructations, sensation of weight or oppression in the upper abdomen, symptoms of chronic dyspepsia, biliousness, yellow, sallow, blotched and itchy skin, gas in the intestines crowding the heart causing palpitation and unpleasant sensations around the heart, yellow jaundice; catarrhal irritation, congestion and underfunctioning of the liver, gall bladder, and gall ducts; that it would effect improvement in the biliary functions of the liver and gall bladder and in the drainage of bile from these organs and the entire gall tract; would improve the functions of the drainage of bile from weakened, sluggish organs; would improve the distress due to catarrhal irritation and functional impairment; would relieve and prevent misery caused by functional disorders of the liver glands or by irritation of the gall bladder due to thickened bile; would tend to reduce irritation and congestion, alleviate discomfort, and allay the catarrhal condition; would promote a more wholesome condition, increase the flow of bile, assist Nature in its healing work; and that it would produce beneficial results in a very short time, were false and misleading since it would not be efficacious for the purposes recommended. (2) In that the coined word "Regol," appearing on the label as a designation for it, was a false and misleading device meaning to the purchaser that the drug would be effective for the purposes named hereinbefore and that it had acquired such a meaning from the above-named circulars which were distributed to purchasers.

On January 27, 1941, the claimant having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

503. Misbranding of Remas Oil of Herbs. U. S. v. 38 Bottles of Remas Oil of Herbs. Default decree of condemnation and destruction. (F. D. C. No. 3263. Sample No. 33065-E.)

On October 21, 1940, the United States attorney for the District of Massachusetts filed a libel against 38 bottles of Remas Oil of Herbs at Boston, Mass., alleging that the article had been shipped by the Requa Manufacturing Co. from Brooklyn, N. Y., on or about August 20, 1940; and charging that it was misbranded. It was labeled in part: "Remas Oil of Herbs (formerly Rheumaster)."

Analysis of a sample of the article showed that it consisted of oils such as sassafras oil and the oils of coniferous trees.

The article was alleged to be misbranded in that the statements on the bottle label, carton, and in an enclosed circular regarding its efficacy in the treatment of rheumatism or neuritis, were false and misleading since it would not be efficacious for such purposes.

On November 25, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

504. Misbranding of Tonico Fir-Veta. U. S. v. 68 Bottles of Tonico Fir-Veta. Default decree of condemnation and destruction. (F. D. C. No. 3845. Sample No. 7617-E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter and falsely represented that it complied with the law. The carton containing the bottle was considerably larger than was necessary.

On February 21, 1941, the United States attorney for the Southern District of California filed a libel against 68 bottles of Tonico Fir-Veta at Los Angeles, Calif., alleging that the article had been shipped in interstate commerce on or about November 25, 1940, by El Modelo Medicine Co. from San Antonio, Tex.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of strychnine and quinine salts, small proportions of iron, calcium, manganese, and potassium compounds including hypophosphites, alcohol, and syrup.

The article was alleged to be misbranded in that its labeling bore representations that it would be efficacious to promote, retain, and insure health; that it would greatly aid Nature in her work in keeping one well, and would restore health, thus bringing lasting happiness; that it would be efficacious to rebuild children, increase their resistance and enable them to gain weight, would relieve children of overtension, and cause them to sleep more restfully; that it would be efficacious to tone up the system, stimulate or restore the appetite, and enable one to gain additional energy; that it would prevent tired nerves, disordered stomach, sluggish bowels, loss of appetite; and that it would be efficacious to keep the nerves fit and increase the vitality of working girls, which were false and misleading, since it would not be efficacious for such purposes.

It was alleged to be misbranded further in that the following statements in the labeling, "El Modelo Medicine Co. has complied with the new Federal Food, Drug, and Cosmetic Act. * * * The laws regulating the manufacture and sale of Drugs and Medicines for your protection, the new Federal Food, Drug, and Cosmetic Act, have been fully complied with, by 'El Modelo Medicine Co.'," were false and misleading since it was not marketed in compliance with the Federal Food, Drug, and Cosmetic Act. It was alleged to be misbranded further in that its container (carton) was so made, formed, or filled as to be misleading.

On April 4, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

505. Misbranding of Torso Herb Vitamin. U. S. v. 2 Bottles of Torso Herb Vitamin. Default decree of condemnation and destruction. (F. D. C. No. 895. Sample No. 75468–D.)

On November 9, 1939, the United States attorney for the Northern District of Ohio filed a libel against 2 bottles of Torso Herb Vitamin at Cleveland, Ohio, alleging that the article had been shipped in interstate commerce on or about October 11, 1939, by John Walters from Baltimore, Md.; and charging that it was misbranded.

Analysis showed that it consisted essentially of a fatty oil, an organic sulfur compound, turpentine oil, cade oil, methyl salicylate, and extracts of plant drugs including aloe, ginger, alcohol, and water.

The article was alleged to be misbranded in that the statement on the label, "used for: Nephritis, diabetes, dropsy, * * * high blood pressure, kidney and bladder, helps stomach," was false and misleading since it would not be efficacious for such purposes.

On January 23, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

506. Misbranding of Kephart's for Hair and Scalp. U. S. v. 140 Bottles, 37 Bottles, and 5 Bottles of Kephart's for Hair and Scalp. Default decree of condemnation and destruction. (F. D. C. No. 3102. Sample No. 6543–E.)

On October 1, 1940, the United States attorney for the District of Colorado filed a libel against 140 3-fluid-ounce bottles, 37 8-fluid-ounce bottles, and 5 32-fluid-ounce bottles of Kephart's for Hair and Scalp at Denver, Colo., alleging that the articles, which had been consigned by Kephart's (H. & E. Foor Co.), had been shipped on or about September 7, 1940, from Los Angeles, Calif.; and charging that it was misbranded.

Analysis of a sample of the article showed that it contained a small proportion of methyl salicylate dissolved in a mixture of mineral oil and saponifiable oils.

The article was alleged to be misbranded in that the following statements and designs in the labeling, "[Series of pictures showing children with various amounts of hair on their heads] Before * * * After Six Weeks * * * After Ninety Days * * * 'This case used only Kephart's (after trying various other treatments with no improvement). The picture tells the whole story.—Berkeley, California.' * * * Before * * * After 90 days * * * After 12 months * * * 'After consulting physicians who were unable to advise any beneficial treatment, our daughter's pictures show the amazing improvement since using Kephart's.—Livingston, Montana,'" were false and misleading since it was not effective in promoting the growth of hair.

On December 5, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

507. Misbranding of Locao Belem. U. S. v. 74 Bottles and 49 Bottles of Locao Belem. Consent decree of condemnation; product ordered released under bond. (F. D. C. No. 3447. Sample Nos. 32807–E, 32808–E.)

On December 2, 1940, the United States attorney for the Southern District of California filed a libel against 74 3-ounce bottles and 49 6-ounce bottles of Locao Belem at Los Angeles, Calif., alleging that the article had been shipped on or about November 1, 1940, by the Belem Products Co. from Houston, Tex.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted chiefly of water, alcohol, a foam producer, a small amount of glycerin, and perfume materials.

The article was alleged to be misbranded in that statements in the labeling representing that it was efficacious in the treatment of baldness, falling hair, dandruff, and irritated scalp; that ordinarily dandruff or itching scalp would respond quickly to treatment with it and that satisfactory improvement or even complete elimination of these conditions would result in from 2 to 4 weeks; that it would bring about improvement in the less severe cases of falling hair in a few weeks and would be efficacious to correct the more severe cases of falling hair in from 3 to 6 months; and that it would be efficacious to develop new growth on bald areas, were false and misleading since it would not be efficacious for such purposes.

On December 23, 1940, Belem Products Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law under the supervision of the Food and Drug Administration. Subsequently, the product was relabeled to conform to the requirements of the Food, Drug, and Cosmetic Act.

508. Misbranding of Parisian Style Saje. U. S. v. 9 Dozen Bottles of Parisian Style Saje. Default decree of condemnation and destruction. (F. D. C. No. 3217. Sample No. 4575–E.)

This product contained no ingredient or combination of ingredients that would produce the effects indicated below. It also was deceptively packaged in that the bottle had been placed in a carton that was twice as large as would have been necessary to hold it.

On or about October 23, 1940, the United States attorney for the Northern District of Illinois filed a libel against 9 dozen bottles of Parisian Style Saje at Chicago, Ill., alleging that the article had been shipped by Giroux Manufacturing Co. from Buffalo, N. Y., on or about March 29, 1940; and charging that it was misbranded.

Examination of a sample of the article showed that it consisted essentially of water, alcohol, glycerin, and small amounts of resorcinol, volatile oils, and capsicum.

The article was alleged to be misbranded in that the following statements were false and misleading since it was not efficacious for the purposes recommended: (Carton) "To aid normal hair growth use Parisian Style Saje daily, rubbing it well into the scalp so that it can soak into the pores and stimulate the superficial circulation * * * For helping the natural growth of the hair"; and (bottle) "Use often to help keep the scalp stimulated * * * and aid the natural hair growth."

It was alleged to be misbranded further in that its container was so made, formed, or filled as to be misleading.

The article was also alleged to be misbranded under the provisions of the law applicable to cosmetics, as reported in C. N. J. No. 66.

On January 23, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

509. Misbranding of skin stimulant and texture oil. U. S. v. 114 Bottles of La Bonita Hollywood Skin Stimulant and 24 Bottles of La Bonita Hollywood Texture Oil. Decree of condemnation and destruction. (F. D. C. Nos. 4865, 4866. Sample Nos. 65607–E, 65608–E.)

On June 9, 1941, the United States attorney for the District of Colorado filed a libel against the above-named products at Denver, Colo., which had been consigned by the House of Hollywood, alleging that the articles had been shipped in interstate commerce on or about May 2, 1941, from Los Angeles, Calif.; and charging that they were misbranded.

Analysis showed that the skin stimulant consisted essentially of alcohol, glycerin, perfume, and coloring matter; and that the texture oil was essentially a perfumed vegetable oil.

La Bonita Hollywood Skin Stimulant was alleged to be misbranded in that the name "Skin Stimulant" was false and misleading, since the article contained no ingredient capable of stimulating the skin.

La Bonita Hollywood Texture Oil was alleged to be misbranded in that the name "Texture Oil," together with the statements "Pat into the neck and jaw line using a brisk slapping motion with the back of the hand. Non-fattening," were false and misleading since they gave the impression that it would affect the structure of the skin; whereas it would not.

Both articles were alleged to be misbranded under the provisions of the law applicable to cosmetics, as reported in notices of judgment on cosmetcs.

On June 27, 1941, the House of Hollywood, Los Angeles, Calif., having signed an acceptance of service and authorization for taking of final decree, judgment of condemnation was entered and the product was ordered destroyed.

510. Misbranding of Alimentone Powder and Alimentone Tablets. U. S. v. 2 Tins of Alimentone Powder and 11 Tins of Alimentone Tablets. Default decree of condemnation and destruction. (F. D. C. No. 3555. Sample Nos. 32625–E, 32626–E.)

Both of these products were falsely represented to be effective in the treatment of overweight and of certain diseases of the mucous membranes.

On January 6, 1941, the United States attorney for the District of Arizona filed a libel against the above-named products at Tucson, Ariz., alleging that they had been shipped by Thomas E. Collins Co., from San Francisco, Calif., on or about July 15, 1940; and charging that they were misbranded.

Analyses of samples of the articles showed that the Alimentone Powder consisted essentially of a spray-dried product such a spray-dried skim milk, embryonic tissues such as wheat germ, and dried green leafy and stemmy material such as garden vegetables; and that the Alimentone Tablets consisted essentially of embryonic tissues such as wheat germ and dried green leafy and stemmy material such as garden vegetables.

The Alimentone Powder was alleged to be misbranded in that the statement on the label, "If overweight, take between meals on an empty stomach," was false and misleading since it was not a suitable, appropriate, or effective treatment for overweight.

The Alimentone Tablets were alleged to be misbranded in that statements on the label, "Take 5 tablets after each meal and 5 at bed time. If overweight, take between meals on an empty stomach. In cases of asthma, start with 2 tablets after each meal for the first five days. Then take 3 tablets after meals for the next five days. Then 4 tablets for the next five days. Then continue with 5 tablets four times daily," were false and misleading since they did not constitute an appropriate treatment for cases of overweight or asthma.

Both products were alleged to be misbranded in that statements in an accompanying circular, entitled "Help Nature," which represented that they constituted treatments for overweight; that they would give relief in colds, catarrh, asthma, bronchitis, hay fever, mucous colitis, vaginal catarrh, and other catarrhal conditions; that they would be effective in maintaining the normal flow of secretions from the mucous membranes and would continually flush away any impurities which might lodge in cell tissues; that they would supply those nutritional elements required by the body to actively maintain its defensive reaction against impurities and bacteria in cell tissue; that they would keep the membranes in a healthy condition; and would eliminate toxic deposits from tissues in bronchial asthma, were false and misleading since they would not be efficacious for such purposes.

On February 21, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

511. Misbranding of Oomph candy. U. S. v. 11 Dozen Boxes of Oomph Candy. Default decree of condemnation and destruction. (F. D. C. No. 3463. Sample No. 31214–E.)

This candy, which was offered as an aid to reduction of weight, had essentially the same composition, was wrapped and packed like, and possessed approximately the same caloric value as ordinary candy.

On December 4, 1940, the United States attorney for the Eastern District of Wisconsin filed a libel against 11 dozen boxes of Oomph candy at Milwaukee,

Wis., alleging that the article had been shipped on or about October 21, 1940, by Nu-Pak-Ej, Inc., from Chicago, Ill.; and charging that it was misbranded. It was labeled in part: "'Oomph' Candy and Reducing Program."

Analysis of a sample of the article showed that it consisted essentially of sugars, protein, fat, soybean flour, and small amounts of sodium chloride, phosphates, and calcium compounds.

The article was alleged to be misbranded in that representations in the labeling that it would be efficacious in the safe reduction of weight; that when used in conjunction with the dietary program included in the labeling, it would provide a proper method of "slenderizing" or losing excessive weight, were false and misleading since it would not be efficacious for such purposes.

It also was alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2537.

On January 23, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

512. Misbranding of Mineralaid. U. S. v. 48 Packages of Mineralaid. Default decree of condemnation and destruction. (F. D. C. No. 4236. Sample No. 11250-E.)

On April 7, 1941, the United States attorney for the Southern District of Texas filed a libel against 48 packages of Mineralaid at Houston, Tex., alleging that the article had been shipped by W. L. Jameson from Denver, Colo., on or about March 17, 1941; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of silicates, small proportions of iron and calcium compounds, sulfates, a trace of fluorides, and nondescript organic matter.

The article was alleged to be misbranded in that statements in the labeling which represented that it would be efficacious to give the user health; that it would afford relief in cases of hay fever, asthma, sinus trouble, nervousness, arthritis, goiter, stomach ulcers, lumbago, anemia, prostate trouble, neuritis, disorders of the liver, kidney and bladder, cancer, acne, acidity, bronchial affections, diabetes, rundown conditions, poor hearing, infantile paralysis, stroke, heart leakage, partial paralysis, varicose veins, pyorrhea, colds, sciatica, rheumatism, hemorrhoids, cataracts, old-age ailments, ringworms and athlete's foot, pregnancy, pneumonia, and angina pectoris; and that it would reduce weight and correct dietary mineral deficiencies, were false and misleading since it would not be efficacious for such purposes.

On May 26, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

513. Misbranding of Merlek Mineral Water. U. S. v. 32½ Cases of Merlek Mineral Water. Trial by jury; verdict for the Government. Judgment of condemnation and destruction. (F. D. C. No. 2234. Sample No. 7292-E.)

On June 22, 1940, the United States attorney for the District of Arizona filed a libel against 32½ cases of Merlek Mineral Water at Phoenix, Ariz., alleging that the article had been shipped in interstate commerce on or about May 18, 1940, by Lee Bros. from Oakland, Calif.; and charging that it was misbranded.

Analysis showed that the article had the approximate composition of sea water.

It was alleged to be misbranded in that the statement on the bottle label, "Merlek is sold only to help supply minerals for mineral deficiencies," was false and misleading as applied to an article that had the approximate composition of sea water. It was alleged to be misbranded further in that representations appearing in an accompanying circular entitled "Have You Eaten Today? Did You Get the Necessary Minerals?" which recommended it for persons who were "cross, tired, misbehaving, naughty," or suffering from nervous collapse, excess acid, run-down conditions, and many other diseases, and that it was valuable in the maintenance of health, for proper growth, for the teeth, for the blood and for life, were false and misleading when considered in the light of its composition and the dosage recommended.

It was also charged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2824.

On July 20, M. E. Lee and Ned Johnson, claimants, filed an answer to the libel admitting the shipment in interstate commerce but denying that the product was a drug or that it was misbranded when shipped in interstate commerce. On December 10, 1940, the case came up for trial before a jury.

The taking of testimony was concluded on December 19, 1940, on which date the court delivered the following instructions to the jury:

THE COURT: "It now becomes the court's duty, gentlemen, to instruct you as to the law that applies to this particular controversy.

"This case was brought under the provisions of the Federal Food, Drug and Cosmetic Act, which is intended to prevent the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics. The statute provides, among other things, that 'any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into, or while in interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter,' and shall be liable to seizure and condemnation.

"The act also provides that interested persons may claim property so seized, and 'that on demand of either party, any issue of fact joined in any such case shall be tried by a jury.'

"In this case, the Government has caused 12 2-quart jugs of an article known as Merlek Mineral Water to be seized. The Government, in its libel filed in the case, has alleged the article to be misbranded in violation of the statute, and Mr. M. E. Lee, of Oakland, Calif., and Mr. Ned Johnson, of Phoenix, Ariz., who have claimed the property under seizure, have denied in their answer filed in this case that the article is misbranded in violation of the statute.

"There is no dispute that the goods under seizure were shipped in interstate commerce by Lee Bros. from Oakland, Calif., to Mr. Ned Johnson, Phoenix, Ariz., on or about May 18th, 1940, or that they were in the possession of Mr. Ned Johnson, of Phoenix, Ariz., when they were seized. I, therefore, charge you that the sole question for you to determine, from the evidence in the case, is whether or not the article under seizure is misbranded in violation of the statute, as alleged by the Government.

"If you find from the evidence that the article is misbranded, then your verdict should be for the Government. If you find from the evidence that the article is not misbranded, then your verdict should be for the claimants.

"This action is one of rem: that is, the Government's complaint is against the Merlek Mineral Water that has been seized, and not against the gentlemen that have appeared to claim it. The intent of the claimants has no bearing on this case. Your part in this proceeding is to determine a question of fact. This question of fact is very simple. Is this water misbranded because of false or misleading statements made about it in the label and circular that has been received in evidence? You are entitled to read and consider the statements made about this water in the label and in the circular, and decide whether or not they are false and misleading in any particular.

"You gentlemen would have no objection to the jury taking the exhibits into the jury room?"

Mr. PERRY: "No, your honor."

Mr. WOOD: "No, your honor."

THE COURT: "Very well. In reaching your decision, you should take into consideration the nature of this water and what it is composed of. Under the law, this water can be considered both a food and a drug. The reason for this is that the directions for its use recommend that some of it be placed in drinking water or in milk. Drinking water and milk are both foods under this law, and anything used as a compound of a food is also declared to be a food. If you should find that the water is also intended for use in the treatment and prevention of mineral deficiency diseases of the human body, it would then also be a drug under the law. So, no matter whether you believe that Merlek Mineral Water is a food or a drug, or both a food and drug, your duty is the same, that is, to decide whether or not it is misbranded, as alleged in the libel.

"In reaching a determination as to whether or not the water is misbranded, you should base your decision entirely on the evidence you have seen and heard at this trial, and should be guided by no other considerations.

"If you decide that this water will do all the things that are claimed for it in the label and circular, and that the labeling is not false and misleading in any respect, you should render a verdict for the claimants; but if you should find from the evidence that while the water may be of help in doing some of the things claimed for it in the label and circular, if you find that it will not do all of the things claimed for it, and that in such respect the labeling is false or misleading, it is your duty to find the water to be misbranded, and your verdict should be for the Government. That is the libelant.

"The statute under which this case has been tried condemns every statement in the labeling of the article Merlek Mineral Water which may mislead or deceive. Deception may result from the use of statements not technically false, or which may be literally true. The aim of this statute is to prevent that resulting from

indirection and ambiguity, as well as from statements that are false. It is not difficult to choose statements that will not deceive.

"If you find from the evidence that there are any false and misleading statements in the labeling involved in this case, your verdict should be for the Government, as I have stated before.

"In determining whether or not any statements made in the labeling of the article Merlek Mineral Water are misleading, you should take into account, among other things, not only representations made or suggested by such statements, but also the extent to which the labeling may fail to reveal facts material in the light of such representations.

"If you find from the evidence that there is a material weight of medical and scientific opinion contrary to any of the representations made in the labeling of Merlek Mineral Water, and no mention is made of the existence of such contrary opinion in said labeling, you may find that said article is misbranded.

"The law casts upon the Government the burden of proving this case by what is known as the preponderance of evidence. Preponderance of evidence simply means the greater weight of the evidence. It is not dependent upon the number of witnesses who have testified in the case, but it is rather the quality of the evidence instead of the—or the quality rather than the quantity. If the evidence should be in your minds equally divided, then the Government, of course, hasn't sustained this burden of proof, and your verdict should be for the claimants.

"You are the sole judges of the credibility of the witnesses; that is to say, the extent to which you will believe the witnesses who have testified before you. It is your duty to reconcile the conflicting testimony of various witnesses and conflicting statements, so far as it may reasonably be done.

"Witnesses, those who are supposed to know more than the ordinary person about such subjects, such as chemists and physicians, have been permitted to give their opinions as to various matters. Opinion evidence is not binding upon you, but should be considered in connection with all other evidence in the case. Should you believe it, you may accept and follow it. By an opinion, I mean a statement or a conclusion arrived at by the witness from experience or from knowledge, as distinguished from testimony concerning the direct fact.

"That is, I might say that this building was constructed of brick. That would be a statement of fact. If I'd say it was worth twenty thousand or a hundred thousand dollars, that would merely be my opinion.

"You are the sole judges of the value of opinion evidence. Of course, an opinion is worthless unless it is the honest opinion of the man who states it. If you deem it is his honest opinion, then its value depends upon how much he knows about the subject concerning which he is testifying. If he is fairly experienced, fairly grounded in his subject, if his opinion is the result of mature reflection, if he is a man of strong logical intellect, his opinion would be entitled to great value. If, on the other hand, he was incapable of logical thinking, or if he was not well grounded in his subject, nor familiar with the facts upon which his conclusion is assumed to be based, then, of course, his opinion would be of little or no value; and it is for you to decide what value you will give to the opinion evidence that you have heard.

"Now, a great deal of the evidence of the witnesses who have testified concerning their own ailments is in the nature of opinion evidence. Those witnesses who testified that they had well known, easily discernible diseases, or easily told diseases, I will say, such as headaches and constipation, or something of that sort, of course, there will be very little reason to doubt that they knew what they had. But if one testified that he thought that he had some more obscure disease, more difficult to diagnose, and his diagnosis of what he had depended entirely upon his own opinion, and he was unable to make such a diagnosis, his opinion would be of very little value. Those are matters for you to take into consideration in weighing the testimony of the witnesses.

"You may also consider the interest of the witnesses, if they have any, in the outcome of the case, their affiliation with either of the parties, their manner of testifying, their appearance upon the witness stand, whether their testimony was logical or otherwise, these and any or all other subjects touching the credibility of the various witnesses, you may take into consideration; and having considered all matters, you will give the testimony of each and every witness such weight as you find it is entitled to receive. That is entirely within your province, and if upon a consideration of all the evidence you find that the statements charged in the libel are false in any substantial part, you will find the product to be misbranded. Upon the other hand, if you do not find that the statements

charged in the libel are false, then, of course, your verdict should be for the claimants, and you will find that the article has not been misbranded.

"Any suggestions, gentlemen, or any objections?"

Mr. PERRY. "No, your honor."

Mr. WOOD. "No, we have none."

THE COURT. "Forms of verdict have been prepared for your guidance. One form reads: 'We, the jury, duly empaneled and sworn in the above entitled action, upon our oaths do find for the libelant.' The libelant, you understand, is the Government.

"The other one: 'We, the jury, duly empaneled and sworn in the above entitled action, upon our oaths do find for the claimants, Mr. Johnson and Mr. Lee.'

"After you retire to your jury room, you will select one of your number to act as your foreman, and proceed with your deliberations. After you have agreed upon a verdict, you will have it signed by your foreman and returned to open court. Any verdict agreed upon must, as you know, be unanimous. Swear the bailiffs."

The jury, after deliberation, returned a verdict for the Government and on January 6, 1941, judgment was entered condemning the product and ordering that it be destroyed.

514. Misbranding of Elsaco Mineralized Water. U. S. v. 100 Bottles of Elsaco Mineralized Water. Default decree of condemnation and destruction. (F. D. C. No. 3602. Sample No. 32657–E.)

On January 2, 1941, the United States attorney for the District of Arizona filed a libel against the above-named product at Phoenix, Ariz., alleging that it had been shipped by the Electrovita Co. from Redwood City, Calif., on or about December 3, 1940; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of lime water containing traces of sulfates and chlorides and a small amount of potassium iodide.

The article was alleged to be misbranded: (1) In that the combination of letters "Elsaco," appearing on the bottle label, constituted a false and misleading device since as a result of statements in a leaflet entitled "Elsaco Mineralized Water A Biologically Pure Mineral Water," which had been shipped by the Electrovita Co. on or about August 10, 1940, and was distributed by one of its agents, the said combination of letters meant to purchasers that the article was an appropriate and effective treatment for run-down, nervous condition, arthritis, swollen, stiff and painful joints, gall-bladder trouble, headaches, nervousness, mucous colitis, ulcer of the stomach, neuritis, stomach and kidney trouble, sinus trouble, toxic diseases, severe intestinal trouble, nerve trouble, rheumatism, eczema, pleurisy, varicose veins, asthma, chronic fistula, ulcerated colitis, anemia, gallstones, tumors, weak eyes, hemorrhages, and that it was "one of the greatest means for the rebuilding of the body tissues, cell life, and blood that has yet been discovered"; whereas it was not an appropriate or effective remedy for the disease conditions listed nor was it a means of rebuilding the body tissue, cell life, and blood. (2) In that statements in the aforesaid circular were false and misleading as applied to an artificially prepared mineral water; the labeling failed to reveal that any treatment by electrolysis to which the water had been subjected had had any significant result on its therapeutic or curative effects, a fact material in the light of the statement that the article had been treated by electrolysis and that it contained electrically treated mineral elements; and that the article contained but inconsequential proportions, if any, of many of the elements listed.

On February 6, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

515. Misbranding of mineral water. U. S. v. 9 Bottles and 12 Bottles of McFadden 3 Sisters Springs Mineral Water. Default decree of condemnation and destruction. (F. D. C. No. 2814. Sample No. 15891–E.)

On September 13, 1940, the United States attorney for the Eastern District of Missouri filed a libel against 9 1-gallon bottles and 12 5-gallon bottles of mineral water at Flat River, Mo., alleging that the article had been shipped from McFadden 3 Sisters Springs, Hot Springs National Park, Ark., on or about August 8, 1940; and charging that it was misbranded.

Examination showed that the article contained calcium bicarbonate (2.77 grains per quart) and smaller proportions of other mineral constituents commonly found in ground waters.

The article was alleged to be misbranded in that statements in the labeling which represented and suggested that it was efficacious in the treatment of Bright's disease, diabetes, dropsy, pus in kidney, bladder and urethra, and other kidney, bladder, and urinary troubles, high and low blood pressure, enlarged prostate gland, paralysis, stones in kidney, and other urinary troubles, change of life, female irregularities, insomnia, anemia, nervous prostration, gout and hyperacidity; that this drug would be efficacious to maintain and restore health in apparently hopeless cases and to rejuvenate shattered nerves and weakened bodies; that it possessed the health giving properties implied in the statement "Fountains of Health"; that it was efficacious in advanced stages of kidney trouble, bladder and gall-stone misery, cystitis, rheumatism, arthritis, sciatica, diabetes, chronic constipation and resulting complications; that it would bring about renewed vitality and fitness; that it would be efficacious to help nature to discharge toxins which frequently cause serious ills and to flush out accumulated wastes which form poisons to attack the vital organs, the liver, kidney, and bladder; that it would be efficacious in cases of faulty elimination and poor assimilation; that it would assist nature in the cleansing of each tissue, nerve and muscle, thus enabling nature's recreating and rejuvenating forces to carry new life thereto; that said drug would be efficacious to control the changes in tissue which produce old age and infirmities and enable one to catch the rhythm of youth again; and that this drug would supply the minerals to keep the body tissues and fluids and organs in perfect running order, clarify the blood, promote physical repair, and eliminate waste, were false and misleading since the article would not be efficacious for such purposes.

On October 31, 1940, no claimant having appeared, judgment of condemnation was entered, and the product was ordered destroyed.

516. Misbranding of Thermo-Roller. U. S. v. 9 Retail Packages of Electrically Heated Thermo-Roller. Default decree of condemnation and destruction. (F. D. C. No. 1798. Sample No. 3021–E.)

This product was a device made in the form of a rolling pin covered with corrugated rubber and was electrically heated. Its labeling bore false and misleading representations regarding its efficacy as a reducing agent and in the treatment of certain diseases.

On April 11, 1940, the United States attorney for the Western District of Pennsylvania filed a libel against 9 packages of the above-named product at Pittsburgh, Pa., alleging that the article had been shipped in interstate commerce on or about February 24, 1940, by the Thermo-Roller Corporation from New York, N. Y.; and charging that it was misbranded.

The article was alleged to be misbranded in that representations in the labeling that it would enable one to achieve a completely balanced figure without special effort by concentrating on the spot or area most out of proportion; that it would be efficacious to reduce the abdomen, hips, thighs and "dowager's hump" between the shoulders and remove localized deposits of fat; that it was efficacious in reducing excessive external fat; it would be efficacious in eliminating fat cell elements; and that it would be beneficial in the treatment of sciatica, rheumatism, arthritis, lumbago and other common nervous disorders were false and misleading since the article would not be efficacious for such purposes.

On May 6, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

517. Misbranding of Axine Plates. U. S. v. 50 Pairs of Axine Plates (and 3 other seizures of Axine Plates). Default decrees ordering that the product be destroyed. (F. D. C. Nos. 3430, 3615, 3799, 4085. Sample Nos. 35471–E, 37110–E, 43164–E, 57237–E.)

Between November 27, 1940, and March 22, 1941, the United States attorneys for the Middle District of Tennessee, Western District of Oklahoma, and the Southern District of Texas filed libels against 50 pairs of Axine Plates at Nashville, Tenn., 18 pairs at Pearson, Okla., and 12 pairs at Houston, Tex., alleging that the article had been shipped on or about July 9, 1939, and July 12 and 27, 1940, by W. Gordon Pervis from Tennille, Ga.; and charging that it was misbranded. On April 1, 1941, the United States attorney for the Eastern District of Illinois filed a libel against 79 Axine Plates at West Frankfort, Ill., which had been consigned by W. Gordon Pervis, alleging that the article had been shipped from Tennille, Ga., on or about December 13, 1938; and charging that it was misbranded.

Examination showed that each of these devices consisted of two metal plates, one made of copper and the other of zinc, which were to be worn in the shoes of the user, a plate in each shoe.

The article was alleged to be misbranded in that the combination of letters "Axine," imprinted on each plate, was false and misleading since by reason of a leaflet entitled "Health Without Medicine," which accompanied each pair of plates, it indicated to purchasers that wearing of these plates would bridle and force human electricity to rid the blood of uric acid, thereby constituting an effective and appropriate treatment for high blood pressure, low blood pressure, headache, asthma, paralysis, kidney trouble, rheumatism, diabetes, eczema, cold hands and feet, poor circulation, indigestion, hardening of the arteries, enlargement of the heart, blood clots on the brain, and excessive coughing, and that it would usually relieve said troubles within 30 days, and that it would be effective to enable one to feel young again and to relieve prostate gland involvement; whereas the article would not be efficacious for such purposes.

Between January 17 and April 26, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

518. Misbranding of Magnetic Ray appliances. U. S. v. 6 Magnetic Ray Appliances. Default decree of condemnation and destruction. (F. D. C. No. 1937. Sample No. 9493–E.)

This product consisted of a coil made in the form of a belt to which was fastened a wire to be connected with an ordinary lighting current. When so connected it would produce a magnetic field.

On May 11, 1940, the United States attorney for the Eastern District of Louisiana filed a libel against 6 Magnetic Ray appliances at Baton Rouge, La., alleging that the article had been shipped on or about May 1, 1940, by the Magnetic Ray Co. from Dallas, Tex.; and charging that it was misbranded.

It was alleged to be misbranded in that representations in the labeling that it would be efficacious in the treatment of asthma, arthritis, anemia, Bright's disease, bladder trouble. bronchitis, colds, constipation, catarrh, catarrhal deafness, diabetes, deafness, eczema, epilepsy, goiter, hay fever, hemorrhoids, heart diseases, headache, high blood pressure, indigestion, insomnia, impotence, low blood pressure, lumbago, menstrual trouble, neuralgia, neuritis, nervous trouble, obesity, paralysis, pelvic disorders, prostate troubles, rheumatism, sciatica, sinus trouble, tuberculosis, tumors, ulcers and varicose veins; that it would be efficacious in the prevention of disease; that it would increase elimination, promote sound and refreshing sleep, relieve pain, produce relaxation, remove causes which might lead to surgical operations, stimulate various glands and organs, increase physical and mental efficiency, clear the complexion, cause the absorption of growths and deposits, such as tumors, goiter and blood clots; and that it would favorably affect circulation, elimination, digestion, nutrition and metabolism, were false and misleading since it would not be efficacious for such purposes.

On December 20, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

519. Misbranding of Electreat Mechanical Heart. U. S. v. 5 Electreat Mechanical Hearts (and 6 other seizure actions against Electreat Mechanical Hearts). Decrees of condemnation. Portion of product ordered destroyed; remainder ordered released under bond for relabeling. (F. D. C. Nos. 3994, 4005, 4072, 4078, 4079, 4092, 4370. Sample Nos. 5184–E, 32992–E, 32996–E, 35734–E, 40322–E, 50516–E, 60574–E.)

The labeling of this device, which consisted of flashlight batteries, a small electrical coil equipped with a buzzer and attachments for applying electricity to various parts of the body, bore false and misleading representations regarding its curative and therapeutic properties.

Between March 15 and April 16, 1941, the United States attorneys for the Eastern District of Pennsylvania, the District of Columbia, Southern District of California, Northern District of Ohio, and the District of Idaho filed libels against 5 of the above-named devices at Bristol, Pa.; 3 at Washington, D. C.; 13 at Pasadena, Calif.; 6 at Lima, Ohio; 11 at Boise, Idaho, alleging that the article had been shipped in interstate commerce within the period from on or about February 5 to on or about March 14, 1941, by the Electreat Manufacturing Co. from Peoria, Ill. On March 29, 1941, the United States attorney for the Northern District of Texas filed a libel against 27 of the said devices at San Angelo, Tex., which had been shipped by the Electreat Manufacturing Co. from Peoria, Ill., on or about March 14, 1941.

The article was alleged to be misbranded in that the following statements in the labeling, (molded into the device) "Electreat * * * Relieves Pain," (paper disk attached to portion) "Electreat * * * Mechanical Heart," (cartons of portion) "Elec-Treat Mechanical Heart * * * For Relief of Pain and

Muscular Soreness," (massage attachment) "Electreat * * * Relieves Pain," were false and misleading in that the said statements represented that the device would be efficacious for the purposes recommended; whereas it would not be efficacious for such purposes.

On April 4, 17, and 28, and May 7 and 17, 1941, no claimant having appeared for the lots seized at Bristol, Pa.; Washington, D. C.; San Angelo, Tex.; Lima, Ohio; and Boise, Idaho, judgments of condemnation were entered and the product was ordered destroyed.

On September 13, 1941, Mrs. E. C. Jones, claimant for the lot seized at Pasadena, having admitted the allegations of the libel, judgment of condemnation was entered and it was ordered that the product be released under bond conditioned that it be brought into compliance with the law under the supervision of the Food and Drug Administration. This lot was relabeled.

DRUGS ALSO FAILING TO BEAR THE REQUIRED INGREDIENT STATEMENT [4]

520. Misbranding of Sto-Bo-Ki and McClintock's Formula for Diabetes. U. S. v. Robert McClintock. Plea of guilty. Fine, $120; sentence of 1 year and 1 day's imprisonment. Sentence suspended and defendant placed on probation for 3 years. (F. D. C. No. 2884. Sample Nos. 4197-E, 16805-E.)

On December 31, 1940, the United States attorney for the Eastern District of Michigan filed an information against Robert McClintock, Ann Arbor, Mich., alleging shipment from the State of Michigan on or about March 21 and May 24, 1940, into the States of Illinois and Kansas of a quantity of Sto-Bo-Ki and McClintock's Formula for Diabetes that were misbranded.

Analyses of samples of the articles showed that Sto-Bo-Ki consisted essentially of sulfuric acid, alcohol (77.5 percent by volume), and water flavored with aromatics; and that McClintock's Formula for Diabetes consisted essentially of sulfuric acid, alcohol (75.05 percent by volume), and water flavored with cinnamon oil.

Sto-Bo-Ki was alleged to be misbranded in that the statements "The Digestive Remedy * * * Use it only until ailment ceases" were false and misleading since it was not efficacious as a digestive remedy and its use would not cause cessation of digestive ailments.

McClintock's Formula for Diabetes was alleged to be misbranded in that the statement "Formula for Diabetes," borne on the bottle label, was false and misleading since it was not efficacious as a treatment for diabetes.

Both products were alleged to be misbranded further (1) in that the statement (bottle label) "Reg. With U. S. Food and Drug Administration" was false and misleading since they were not registered with the United States Food and Drug Administration; and (2) in that they were fabricated from two or more ingredients and their labels did not bear the common or usual name of the active ingredient, sulfuric acid, nor the quantity, kind, and proportion of alcohol that they contained.

On May 16, 1941, a plea of guilty was entered by the defendant and the court imposed a fine of $120 and a jail sentence of 1 year and 1 day. The jail sentence was suspended and the defendant was placed on probation for 3 years.

521. Adulteration and misbranding of Dr. Senftner's Glucocinine. U. S. v. 27 Boxes and 12 Boxes of Dr. Senftner's Glucocinine. Default decree of condemnation ordering product delivered to Food and Drug Administration for technical use. (F. D. C. No. 4009. Sample Nos. 31575-E, 31576-E.)

On March 21, 1941, the United States attorney for the Eastern District of Michigan filed a libel against the above-named product at Detroit, Mich., alleging that it had been shipped by the Glucocinine Co. of America from Richmond Hill, N. Y., on or about January 20 and 30, 1941; and charging that it was adulterated and misbranded.

Annalysis of a sample of the article showed that it consisted essentially of powdered plant tissues including potato strach.

It was alleged to be adulterated in that its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess, namely: (Carton label) "Ingredients—Plant Insulin substances," (circular entitled "Glucocinine") "(Vegetable Insulin)" and "(Plant Insulin)," and (circular entitled "Glucocinine in Diabetes Mellitus") "Glucocinines are extracted by a special process. The resulting preparation is * * * free from carbohydrates."

[4] Except Nos. 534 and 536. See also Nos. 429, 430, 433-437, 439, 440, 442-444, 446, 450-453, 485.

It was alleged to be misbranded: (1) In that the statements (carton label) "Ingredients—Plant Insulin substances," and (circular entitled "Glucocinine") "(Vegetable Insulin)" and "(Plant Insulin)," were false and misleading. (2) In that representations in the labeling that it was a "plant insulin" which would be efficacious when administered orally in the treatment of diabetes mellitus, that it was "An answer to the intelligent diabetic's prayer," that it was "positively unsurpassed," and that it would help to stimulate the pancreas gland to produce insulin of its own, were false and misleading since it would not be efficacious for the purposes recommended. (3) In that its label failed to bear the common or usual name of each of the active ingredients.

On May 13, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to the Food and Drug Administration for technical purposes.

522. Misbranding of Chase Formula. U. S. v. 4 Gross Packages of Chase Formula. Default decree of condemnation and destruction. (F. D. C. No. 3606. Sample No. 37219–E.)

The label of this product not only contained false and misleading therapeutic claims, but it failed to list the active ingredients in the manner prescribed by law, and it failed to bear an accurate statement of the amount of alcohol present.

On January 2, 1941, the United States attorney for the Southern District of Florida filed a libel against 4 gross packages of Chase Formula at Miami, Fla., alleging that the article had been shipped by the Chase Laboratory from Detroit, Mich., on or about October 15, 1940; and charging that it was misbranded.

Examination of a sample showed that the article consisted essentially of a fatty oil (approximately 16 percent), oleic acid (approximately 5 percent), mineral oil (approximately 2 percent), alcohol (by volume 17.8 percent), a small proportion of triethanolamine, and water.

The article was alleged to be misbranded in that statements in the labeling that it was efficacious for the treatment of athlete's foot, impetigo, Florida sores, poison ivy, body lice, many types of eczema and skin afflictions caused by external infection; that it would relieve itching and burning of hives and shingles; that it was efficacious in the treatment of muck itch, mango poisoning, and other skin afflictions including many types of eczema, were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further (1) in that the statement in the circular "Chase Formula is greaseless" was false and misleading; (2) in that the list of its active ingredients was not placed prominently on the label with such conspicuousness (as compared with other words and statements in the labeling) as to render it likely to be read by the ordinary individual under customary conditions of purchase and use; and (3) in that the package failed to bear a statement of the quantity or proportion of alcohol contained in the preparation since the statement on the carton and jar label, "denatured alcohol (25%)," was incorrect.

On January 27, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

523. Misbranding of Savol and Savol Cream. U. S. v. 39 Packages of Savol and 20 Packages of Savol Cream. Default decrees of condemnation and destruction. (F. D. C. Nos. 3648, 3649. Sample Nos. 19670–E, 19671–E.)

The labels of both of these products, in addition to bearing false and misleading therapeutic claims, also failed to bear the required ingredient and quantity of contents statements. Furthermore, the bottles holding the Savol solution were packed in unnecessarily large cartons.

On January 9, 1941, the United States attorney for the Western District of New York filed libels against the above-named products at Buffalo, N. Y., alleging that they had been shipped by the Savol Chemical Co. from Mercer, Pa., on or about September 3 and October 1 and 30, 1940; and charging that they were misbranded.

Analyses of samples showed that Savol consisted essentially of cresols, alkali soaps, a small amount of phenol, and water; and that Savol Cream consisted essentially of zinc oxide, barium sulfate, and petrolatum, together with perfume materials. Bacteriological examination showed that Savol Cream was not antiseptic.

Savol was alleged to be misbranded in that representations in the labeling that it would be efficacious in the treatment of nasal catarrh, hay fever, bites of animals, and irritation of the throat; and that it would be efficacious as a preventive of infected sores, abscesses, boils, felons, and all complications due to infections, were false and misleading since it would not be efficacious for such purposes. Savol Cream was alleged to be misbranded in that representations in the labeling that it would be efficacious as an antiseptic for cuts, bites of animals, all forms of piles, skin affections in general, sore throat, croup, enlarged glands, boils, felons, ulcers, eczema; or as an after treatment of boils, felons, carbuncles, and erysipelas, were false and misleading since it would not be efficacious for such purposes.

Both products were alleged to be misbranded further (1) in that their labels failed to bear the common or usual names of the active ingredients, and (2) in that the label failed to bear an accurate statement of the quantity of contents. Savol was alleged to be misbranded further in that its container was so made, formed, or filled as to be misleading.

On February 10, 1941, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

524. Misbranding of Waft-Surgical. U. S. v. 19 Bottles of Waft-Surgical. Default decree of condemnation and destruction. (F. D. C. No. 3299. Sample No. 15982-E.)

On October 28, 1940, the United States attorney for the Eastern District of Missouri filed a libel against 6 8-ounce bottles, 6 pint bottles, 6 quart bottles, and 1 gallon bottle of Waft-Surgical at University City, Mo., alleging that the article had been shipped by Waft Products, Inc., from Springfield, Ill., on or about August 31, 1940; and charging that it was misbranded. It was labeled in part: "Waft-Surgical Antiseptic-Disinfectant-Deodorant-Fungicide-Germicide-Parasiticide."

Analysis of a sample of the article showed that it consisted essentially of water, formaldehyde, small amounts of turpineol, and a yellow-green coloring material.

It was alleged to be misbranded in that representations in the labeling that it would be efficacious as an antiseptic, disinfectant, fungicide, germicide or parasiticide in the dilutions suggested: that it would be of value as a wet dressing or irrigation in wounds in these dilutions; that it would penetrate the environment; that it would inhibit disease-producing micro-organisms; that it would be efficacious for the sterilization of surgical instruments and that it would be a reliable fungicide or germicide for animals, were false and misleading since it would not be efficacious for such purposes.

It was alleged to be misbranded further in that the label did not contain the common or usual names of the active ingredients.

On December 7, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

525. Misbranding of Common-Sense Liniment. U. S. v. 22 Large and 45 Small Bottles of Common-Sense Liniment. Default decree of destruction. (F. D. C. No. 3144. Sample No. 16818-E.)

On or about October 7, 1940, the United States attorney for the Western District of Missouri filed a libel against 67 bottles of Common-Sense Liniment at Kansas City, Mo., alleging that the article had been shipped by T. H. Jackson & Co. from Quincy, Ill., on or about August 8, 1940; and charging that it was misbranded.

Analysis of a sample showed that the article consisted essentially of linseed oil, pine oil, guaiacol, paraffin oil, and a small amount of ammonia.

The article was alleged to be misbranded in that certain statements appearing in the labeling were false and misleading since it would not be efficacious for the purposes named in said statements. These statements represented that it was a penetrating, common-sense treatment for ailments of man requiring an external application; that it possessed healing and relieving properties; and that it would be efficacious in the treatment of muscular rheumatism, sciatic rheumatism, nervous headache, lame back, pains in the side and breast caused by colds or injuries, earache, partial deafness caused by cold, roaring in the ear, hardening of the wax and inflammation of the muscles and nerves of the ear, dryness of the ear drum, sore throat and neck, stiff joints and contracted cords, chilblains, frost-bitten and tender feet, corns, soft corns and bunions, sprains, bruises, all cuts, sores, and bites of poisonous insects. The said state-

ments represented that the article would be efficacious in the treatment of horses for all ailments requiring an external application; that when applied to the belly it would assist in drawing the blood to the surface and relieve the tendency to congestion of the bowels; that it had penetrating, healing and relieving properties; that it would allay inflammation, relax the cords and muscles, and aid the circulation of the blood to the diseased parts; that it would be efficacious in the treatment of coffin-joint lameness, sweeny, stone and bruised shoulder, sciatica or hip sweeny, sitfast, sore back, enlargement of the hock, contracted feet or hoof-bound, rheumatism, corns, thrush or rotten frog, scratches or grease-heel, founder, sprung knees, cocked ankles, weak eyes, and sores.

The article was alleged to be misbranded further (1) in that its label did not bear a list of the active ingredients; and (2) in that the label did not bear a statement of the quantity of the contents.

On November 14, 1940, no claimant having appeared, judgment was entered ordering that the product be destroyed.

526. Misbranding of Apex Special Hair Pomade and Apex Pomento. U. S. v. 158 Cans of Apex Special Hair Pomade and 26 Cans of Apex Pomento. Default decree of condemnation and destruction. (F. D. C. Nos. 2345, 2346. Sample Nos. 24011–E, 24012–E, 24013–E.)

These products were both short of the declared weight, and their containers were filled to approximately three-fourths of their capacity. The labeling of the Pomade bore false and misleading representations regarding its efficacy, and also failed to bear a statement of the common or usual names of the active ingredients.

On July 10, 1940, the United States attorney for the Eastern District of Pennsylvania filed a libel against the above-named products at Philadelphia, Pa., alleging that the articles had been shipped on or about July 1, 1940, from Atlantic City, N. J., by the Apex News & Hair Co. Inc.; and charging that they were misbranded.

Analysis of a sample of the Pomade showed that it consisted of a small proportion of coal tar incorporated in petrolatum.

Both products were alleged to be misbranded in that the following statements were false and misleading since they were incorrect: (Pomade) "Net Contents 3 Ozs. [or "Net Contents ¾ Oz."]"; and (Pomento) "Net Contents 1–½ Ozs." Both products were alleged to be misbranded further in that their containers were so made, formed, or filled, as to be misleading. The Pomade was alleged to be misbranded further in that the following statements on the can were false and misleading since they represented that the article was efficacious for the purposes recommended, whereas it was not efficacious for such purposes: (Cans, both sizes) "for stubborn cases of dandruff, thin and falling hair," (cans, 3-ounce size) "It aids * * * in protecting the scalp from minor scalp ailments. Excellent for thin temples." The Pomade was alleged to be misbranded further in that its label failed to bear a statement of the common or usual names of the active ingredients.

On July 29, 1940, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

527. Misbranding of Overnight Hair-A-Gain. U. S. v. 30 Packages of Overnight Hair-A-Gain. Default decree of condemnation and destruction. (F. D. C. No. 3364. Sample No. 45950–E.)

On November 14, 1940, the United States attorney for the District of Oregon filed a libel agaist 30 packages of Overnight Hair-A-Gain at Portland, Oreg., alleging that the article had been shipped on or about October 19, 1940, by Georgia O. George from Los Angeles, Calif.; and charging that it was misbranded.

Examination of a sample showed that the article was essentially a semi-solid soap with tar.

It was alleged to be misbranded in that the following statements appearing on the label created the false and misleading impression that its use would be effective in promoting the growth of hair: "Overnight Hair-A-Gain * * * Blood Grows Hair (This product does not grow hair —The hair growing element comes from the blood) Hair grows from blood." It was alleged to be misbranded further in that the label did not bear the common or usual names of the active ingredients.

On January 9, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

528. Misbranding of Pick-Me-Up Bath and Hangover Bath. U. S. v. 71 Bottles of Pick-Me-Up Bath and 60 Bottles of Hangover Bath. Default decree of condemnation and destruction. (F. D. C. No. 3779. Sample Nos. 50077-E, 50078-E.)

The labeling of these products bore false and misleading representations regarding their efficacy in the conditions indicated hereinafter, and also failed to bear the common or usual names of the active ingredients and the required declaration of alcohol.

On February 6, 1941, the United States attorney for the District of Columbia filed a libel against 65 3-fluid-ounce, 3 12-fluid-ounce, and 3 25-fluid-ounce bottles of Pick-Me-Up Bath and 53 3-fluid-ounce, 4 12-fluid-ounce, and 3 25-fluid-ounce bottles of Hangover Bath at Washington, D. C., alleging that the articles had been shipped in interstate commerce within the period from on or about February 7 to on or about December 21, 1940, by Xandra, Ltd., from New York, N. Y.; and charging that they were misbranded.

Analyses of samples of the articles showed that the Hangover Bath consisted essentially of ammonia (15.7 percent by weight), alcohol (40 percent by volume), water, and a green coloring matter; and that the Pick-Me-Up Bath consisted essentially of ammonia (16.5 percent by weight), alcohol (36 percent by volume), water and green coloring matter.

The articles were alleged to be misbranded in that the following statements on the labels were false and misleading: "Pick-Me-Up Bath" and "Hangover Bath." They were alleged to be misbranded further in that the labels did not bear the common or usual names of the active ingredients and a statement of the quantity or proportion of alcohol contained therein.

They were also alleged to be misbranded in violation of the Federal Caustic Poison Act, as reported in notice of judgment No. 110 published under that act.

On February 27, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

VETERINARY REMEDIES

529. Misbranding of Avirem Poultry Remedy. U. S. v. Henry F. Miller, Roy B. Poppleton, and Dewey K. Cosner (Livestock Products Distributors). Pleas of guilty. Fines, $150. (F. D. C. No. 2867. Sample No. 15575-E.)

The label of this product not only bore false and misleading therapeutic claims, but it also failed to bear a statement of the kind and quantity or proportion of alcohol that was contained in the article.

On April 16, 1941, the United States attorney for the Southern District of Illinois filed an information against Henry F. Miller, Roy B. Poppleton, and Dewey K. Cosner, trading as Livestock Products Distributors at Kewanee, Ill., alleging shipment by said defendants on or about January 6, 1940, from the State of Illinois into the State of Iowa of a quantity of Avirem Poultry Remedy that was misbranded.

Analysis of a sample of the article showed that it consisted essentially of dextrose, small proportions of magnesium sulfate, sodium hydroxide, sodium chloride, extracts of plant drugs including emodin-bearing drugs such as cascara sagrada, nux vomica, and alcohol (3.9 percent by volume), and water.

The article was alleged to be misbranded in that the statements "Rich in Dextrose * * * The Food Value Poultry Remedy * * * Food value induced by the dextrose content * * * will help your laying program. Increased production has been noticed by users everywhere," were false and misleading since it was not high in food value, would not increase egg production, and when used as directed would supply only an insignificant amount of dextrose. It was alleged to be misbranded further in that the name, "Avirem The Food Value Poultry Remedy," and statements in the labeling representing that it was a poultry remedy; that it would be efficacious in the treatment of coccidiosis, cholera, typhoid and other intestinal infections and disorders, of intestinal disturbances of baby chicks, and of worms, respiratory diseases and blackhead; that it would be efficacious to help prevent disease and keep poultry healthy; that it would build resistance and minimize worm infestation; that it would be efficacious in cases of droopiness and loss of color or appetite; and that its daily use would insure quick pick-up and sustained resistance, were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded still further in that its label failed to declare the kind and the quantity or proportion of alcohol contained therein.

On April 22, 1941, the defendants entered pleas of guilty and the court imposed a fine of $50 on each, totaling $150.

530. Misbranding of Pet-Eez. U. S. v. S. De Witt Lount (Pet-Eez Co.). Plea of guilty. Fine, $100. (F. D. C. No. 2876. Sample Nos. 12822–E, 13019–E.)

The labels of both shipments of this veterinary product bore false and misleading therapeutic claims, and that of one shipment bore a false statement regarding its alcohol content.

On December 28, 1940, the United States attorney for the Northern District of California filed an information against S. De Witt Lount, trading as the Pet-Eez Co. at Oakland, Calif., alleging shipment on or about October 2, 1939, and February 1, 1940, from the State of California into the States of Nevada and Washington of quantities of Pet-Eez that was misbranded.

Analyses of samples of the article showed that the portion which was shipped into the State of Nevada consisted essentially of volatile oils including cubeb oil, cinnamon oil, bergamot oil, isopropyl alcohol (12.8 percent by volume), and water; and that the portion shipped into Washington consisted essentially of volatile oils including cubeb oil, cassia oil, isopropyl alcohol (12.4 percent by volume), and water.

The article was alleged to be misbranded in that its labeling bore representations that it was efficacious as a treatment, preventive and cure for distemper; that it was efficacious in relieving the discomforts of colds, coughs, and distemper and would eliminate the danger of coughs, colds, distemper and respiratory ailments in dogs; that it was efficacious in the treatment of chorea, and would restore to health dogs which suffer from chorea and loss of the use of hind quarters; that one or two drops of it in each nostril two or three times a week, when dogs are permitted to run at large or when they come in contact with other dogs, and its administration two or three times a week to puppies up to the age of 1 year, would be an efficacious preventive of disease in dogs and puppies; and that it was a germicide, which representations were false and misleading since it would not be efficacious for the purposes recommended. A portion of the article was alleged to be misbranded further (1) in that the statement "Alcohol 20 per cent," borne on the bottle label, was false and misleading since it contained no ethyl alcohol but did contain isopropyl alcohol; and (2) in that it was fabricated from two or more ingredients and contained isopropyl alcohol, but its label did not state the quantity, kind, and proportion of alcohol, i. e., isopropyl alcohol, that it contained.

On January 14, 1941, the defendant entered a plea of guilty and was fined $100.

531. Misbranding of Harvey's Embrocation or Curb Bottle. U. S. v. 591 Packages of Harvey's Embrocation or Curb Bottle. Consent decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 3912. Sample No. 33018–E.)

On March 6, 1941, the United States attorney for the Southern District of New York filed a libel against 591 packages of the above-named veterinary product at New York, N. Y., alleging that the article had been shipped from Liverpool, England, by Harvey & Co. on or about November 22, 1940; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of an unsaturated oil such as croton oil, ethyl alcohol (63.1 percent by volume), isopropyl alcohol (9.1 percent by volume), and a red coloring matter.

It was alleged to be misbranded in that statements in the labeling that it would be efficacious in the treatment of splint, spavin, and bony enlargements or callosities, or for deep-seated lameness including shoulder lameness, sidebone, ring-bone, bog spavin, thoroughpin, navicular disease, defective horn, ophthalmia, glandular swellings, abscesses, sore throat and cough; that it would penetrate to the bone and therefore would be successful in the treatment of chronic lameness; and that it would go straight to the root of the malady, dissipating the disease without pain or injury; that Harvey's Aconite Powders would be efficacious in the treatment of chronic cough, broken wind, and other diseases of the organs of respiration in horses and cattle; that Harvey's Worm and Condition Powders would eradicate all worms in horses; and that Harvey's Hair-Restoring Ointment for Horses would restore hair in horses, were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further (1) in that the label failed to bear a statement of the quantity and proportion of ethyl alcohol and isopropyl alcohol; and (2) in that its container was so made, formed, or filled as to be misleading.

On April 24, 1941, Kopf Manufacturing Co., Inc., New York, N. Y., claimant, having admitted the allegations of the libel, judgment of condemnation was

entered and the product was ordered released under bond conditioned that the boxes and the enclosed circulars be destroyed and that the bottles be relabeled.

532. Misbranding of McMillan's Nomoppin and McMillan's Demytin. U. S. v. 59 Bottles of McMillan's Nomoppin and 20 Bottles of McMillan's Demytin. Default decree of condemnation and destruction. (F. D. C. No. 3448. Sample Nos. 20924–E, 20925–E.)

On or about December 11, 1940, the United States attorney for the Southern District of Georgia filed a libel against the above-named products at Augusta, Ga., alleging that the articles had been shipped by McMillan Drug Co. from Columbia, S. C., on or about July 17, 1940; and charging that they were misbranded.

Analyses of samples showed that Nomoppin consisted essentially of potassium arsenite and water; and that Demytin consisted essentially of calcium thiosulfate, calcium polysulfide, and water.

McMillan's Nomoppin was alleged to be misbranded in that its labeling bore representations that it was efficacious as a treatment, preventive, and cure for sorehead of poultry; that it was efficacious as a tonic; that it would protect and free hens and chicks from mites; and that it would hasten moulting, brighten plumage, increase egg production, and promote more and stronger chicks, which representations were false and misleading since it would not be efficacious for such purposes. It was alleged to be misbranded further in that its labeling failed to bear an accurate statement of the quantity of contents.

McMillan's Demytin was alleged to be misbranded in that its labeling bore representations that it was efficacious as a preventive of diarrhea of poultry, and that it would free hens from "mites, etc.," promote prompter moulting, brighten plumage, increase egg production, and promote growth, strength and vigor of chicks, which representations were false and misleading since it would not be efficacious for such purposes.

Both articles were alleged to be misbranded further in that their labels failed to bear the common or usual names of their active ingredients, and in the case of Nomoppin the label failed to bear a statement of the quantity or proportion of arsenic that was present.

On January 1, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

533. Misbranding of veterinary remedies. U. S. v. 69 Packages of National Hog Remedy, 45 Packages of National Horse, Cow, and Mule Remedy, and 9 Packages of National Dog Worm Powder. Default decree of condemnation and destruction. (F. D. C. Nos. 2321 to 2323, incl. Sample Nos. 343–E to 345–E, incl.)

On July 8, 1940, the United States attorney for the Western District of Virginia filed a libel against the above-named products at Galax, Va., alleging that they had been shipped on or about May 16, 1940, by the National Hog Remedy Co. from Raleigh, N. C.; and charging that they were misbranded.

Analyses of samples of the articles showed that the Hog Remedy consisted essentially of sodium thiosulfate, sodium chloride, sodium sulfate, sodium bicarbonate, iron sulfate, antimony sulfide, fenugreek, flaxseed meal, charcoal, and lime; the Horse, Cow, and Mule Remedy consisted essentially of sodium chloride, sodium thiosulfate, iron sulfate, antimony sulfide, fenugreek, flaxseed meal, a cereal plant, charcoal, and lime; and the Dog Worm Powder consisted essentially of sodium chloride, sodium thiosulfate, sodium bicarbonate, sodium sulfate, iron sulfate, antimony sulfide, fenugreek, flaxseed meal, and charcoal.

The Hog Remedy was alleged to be misbranded in that representations in the labeling that it was a powerful tonic, flesh builder, and anthelmintic, and that it would be efficacious in the prevention and treatment of disease conditions of swine, were false and misleading, since it would not be efficacious for such purposes.

The Horse, Cow, and Mule Remedy was alleged to be misbranded in that representations in the labeling that it was a medicinal tonic, conditioner, flesh builder, blood alterative or blood purifier, and worm remover, and that it would increase milk production and promote health, were false and misleading, since it would not be efficacious for such purposes.

The Dog Worm Remedy was alleged to be misbranded in that representations in the labeling that it would be efficacious in the removal of all species of worms infesting dogs, were false and misleading, since it would not be efficacious for such purposes.

All products were alleged to be misbranded further in that they were drugs and their labels failed to bear the common or usual name of each active ingredient.

On January 14, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

534. Misbranding of Red-Hed Coxol. U. S. v. 1 Drum and 1 Drum of Red-Hed Coxol. Default decrees of condemnation and destruction. (F. D. C. Nos. 2828, 3836. Sample Nos. 21627-E, 26956-E.)

On September 26, 1940, and February 25, 1941, the United States attorney for the Northern District of California filed libels against 2 50-gallon drums of Red-Hed Coxol at Modesto, Calif., alleging that the article had been shipped on or about August 7 and November 5, 1940, by Production Laboratories from Seattle, Wash.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of mineral oil (61 percent), a saponifiable oil consisting in part of fish oils, turpentine (3 percent), a small amount of iodine, and a red coal-tar dye.

The article was alleged to be misbranded in that the labeling directly and indirectly represented that it was effective as a preventive of and treatment for coccidiosis and blackhead in chickens and turkeys, which representations were false and misleading since it was not effective for such purposes.

On November 16, 1940, and March 18, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

535. Misbranding of Tonik-Kote 4-Use Skin Conditioner and Tonik-Kote Ointment. U. S. v. 115 Cartons of Tonik-Kote 4-Use Skin Conditioner and 69 Cartons of Tonik-Kote Ointment. Consent decree of condemnation. Products ordered released under bond to be relabeled. (F. D. C. No. 4052. Sample Nos. 60207-E, 60208-E.)

On March 28, 1941, the United States attorney for the Western District of Washington filed a libel against the above-named products at Seattle, Wash., alleging that they had been shipped by Gross Laboratories from Portland, Oreg., on or about February 26, 1941; and charging that they were misbranded.

Analyses of samples of the articles showed that the Skin Conditioner consisted of water, alcohol (2.8 percent by volume), and oil, together with small amounts of pine oil, borates, and protein; and that the Ointment consisted of water, oil, soap, protein, and borates, and contained no peroxide.

The Skin Conditioner was alleged to be misbranded: (1) In that representations in its labeling that it was efficacious in the treatment of all types of skin irritations, eczema, ear canker, sore pads, mange, ringworm, and lice on pets and animals, and that it was efficacious as a skin conditioner, were false and misleading since it would not be efficacious for such purposes. (2) In that the label failed to bear a statement of the quantity or proportion of alcohol that it contained, and the common or usual names of its active ingredients.

The Ointment was alleged to be misbranded: (1) In that representations in its labeling that it was efficacious in the treatment of mange, eczema, ringworm, and other skin irritations on dogs and cats, and that it was made from peroxide, were false and misleading; since it would not be efficacious for such purposes, and it was not made from peroxide. (2) In that its label failed to bear the common or usual names of its active ingredients.

On April 24, 1941, Gross Laboratories, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the products were ordered released under bond conditioned that they be relabeled to comply with the law under the supervision of the Food and Drug Administration.

536. Misbranding of Verm A Food. U. S. v. 56½ Dozen Packages of Sellers Verm A Food No. 1 and 39½ Dozen Packages of Sellers Verm A Food No. 2. Default decree of condemnation and destruction. (F. D. C. No. 3243. Sample No. 34540-E.)

On October 19, 1940, the United States attorney for the Southern District of New York filed a libel against the above-named products at New York, N. Y., alleging that the articles had been shipped by Hugh Sellers & Co. from Washington, D. C., on or about September 24, 1940; and charging that they were misbranded.

Analyses of samples of the articles showed that they consisted essentially of meat, cereals, and senna.

They were alleged to be misbranded in that the labeling bore representations that they were efficacious treatments for large roundworms and constipation of

dogs, cats, and foxes, which representations were false and misleading since the articles would not be efficacious for such purposes.

On November 25, 1940, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

DRUGS PACKED IN DECEPTIVE CONTAINERS[5]

537. Misbranding of nasal jelly. U. S. v. 1,332 Packages of Nasal Jelly. Consent decree of condemnation. Product released under bond to be repacked. (F. D. C. No. 3959. Sample No. 60024–E.)

The cartons in which this product was packed were considerably longer and larger than was necessary to hold the tubes.

On March 14, 1941, the United States attorney for the District of Oregon filed a libel against 1,332 packages of nasal jelly at Portland, Oreg., alleging that the article had been shipped on or about December 20, 1940, and January 3, 1941, by the Norwich Pharmacal Co., from Norwich, N. Y.; and charging that it was misbranded in that its containers were so made, formed, and filled as to be misleading. The article was labeled in part: "Nasal Jelly * * * Distributed by Fred Meyer * * * Portland, Oregon."

On May 9, 1941, the Norwich Pharmacal Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and it was ordered that the product be released under bond conditioned that it be repacked under the supervision of the Food and Drug Administration.

NONSTERILE ABSORBENT COTTON

538. Adulteration and alleged misbranding of absorbent cotton. U. S. v. 48 Dozen Packages of Absorbent Cotton. Decree of condemnation. Product ordered released under bond for reconditioning. (F. D. C. No. 3823. Sample No. 43856–E.)

This product had been shipped in interstate commerce and was in interstate commerce at the time of examination, at which time it was found to contain viable micro-organisms.

On February 17, 1941, the United States attorney for the District of Kansas filed a libel against 48 dozen packages, each containing 3 ounces, of absorbent cotton at Wichita, Kans., alleging that the article had been shipped in interstate commerce on or about December 21, 1940, by the Acme Cotton Products Co. from Dayville, Conn.; and charging that it was adulterated and misbranded. It was labeled in part: "Bonita Absorbent Cotton."

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in an official compendium but its quality and purity fell below the standard set forth in that compendium since it was not sterile; whereas the United States Pharmacopoeia requires that the article be sterile.

It was alleged to be misbranded in that statements appearing on the carton, "Sterilized After Packaging" and "For Surgical and Sanitary Uses," were false and misleading as applied to an article which was not sterile but was contaminated with viable aerobic and anaerobic or facultative anaerobic micro-organisms.

On April 26, 1941, the Acme Cotton Products Co., Inc., New York, N. Y., having filed a claim, judgment was entered finding the product adulterated and ordering its condemnation, and it was ordered further that the product be released under bond conditioned that it be brought into compliance with the law under the supervision of the Food and Drug Administration.

539. Adulteration and misbranding of absorbent cotton. U. S. v. 420 2-Ounce and 267 1-Ounce Packages of Absorbent Cotton. Default decree of condemnation and destruction. (F. D. C. No. 4374. Sample No. 35863–E.)

This article had been shipped in interstate commerce and was in interstate commerce at the time of examination at which time it was found to be contaminated with viable micro-organisms.

On April 17, 1941, the United States attorney for the Eastern District of Louisiana filed a libel against 687 packages of absorbent cotton at New Orleans, La., alleging that the article had been shipped in interstate commerce on or about

[5] See also Nos. 451, 477, 492, 504, 508, 523, 526, and 531 for deceptive packaging; and Nos. 429, 433, 434, 436, 437, 439, 443, 445, 449, 451, 452, 522, 523, 525, and 526 for failure to bear required quantity of contents statement.

February 27, 1941, by New Aseptic Laboratories from Columbia, S. C.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia and its purity and quality fell below the standard set forth in that compendium since it was not sterile; whereas the pharmacopoeia defines absorbent cotton as sterilized.

The article was alleged to be misbranded in that the statements appearing on the label "Sterilized after Packaging" and "Absorbent Cotton for First Aid Hospital and Home Use" were false and misleading as applied to an article which was not sterile and therefore was not suitable for first aid, hospital, and home use.

On June 10, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

PROPHYLACTICS

540. Adulteration and misbranding of prophylactics. U. S. v. 41 Gross of Prophylactics (and 21 other seizure actions against prophylactics). Default decrees of condemnation and destruction. (F. D. C. Nos. 3322, 3333, 3353, 3367, 3369, 3386, 3387, 3388, 5605, 5755, 5771, 5798, 5799, 5813, 5843, 5881 to 5884 incl., 5894, 5908, 7080. Sample Nos. 5557–E, 5558–E, 10434–E to 10437–E, incl., 19662–E, 34740–E, 36368–E, 36369–E, 39501–E, 40674–E, 42958–E, 46750–E, 48610–E to 48621–E, incl., 50039–E, 50041–E, 51583–E, 51587–E, 51993–E, 51994–E, 62561–E, 62565–E, 74123–E, 74124–E, 74397–E, 74398–E, 74399–E.)

Samples of this product were found to be defective because of the presence of holes.

Between November 4, 1940, and March 20, 1942, the United States attorneys for the Southern District of New York, District of Columbia, Eastern District of Missouri, Western District of New York, District of Rhode Island, Western District of Pennsylvania, Northern District of Georgia, Southern District of Ohio, District of Massachusetts, Northern District of Illinois, District of Puerto Rico, and the Eastern District of Pennsylvania filed libels against 545½ gross of prophylactics at New York, N. Y.; 80¾ gross at Washington, D. C.; 114 gross at St. Louis, Mo.; 84 gross at Buffalo, N. Y.; 195 gross at Providence, R. I.; 49 gross at Pittsburgh, Pa.; 487½ gross at Atlanta, Ga.; 123½ gross at Cincinnati, Ohio; 98 gross at Boston, Mass.; 48 gross at Fall River, Mass.; 98¼ gross at Chicago, Ill.; 11 gross at San Juan, P. R., and 20 gross at Philadelphia, Pa., alleging that the article had been shipped in interstate commerce by the Allied Latex Corporation from East Newark, N. J., within the period from on or about October 5, 1940, to on or about February 18, 1942; and charging that it was adulterated and misbranded. The article was labeled variously in part: "Prophylactic," "Smithies," "Thin-Tex," "Gems," "Liquid Latex," "Diana," "Seal-Test," "Dr. Robinson Rx 333," or "Kleenette."

The product in all lots was alleged to be adulterated in that its quality fell below that which it was represented to possess.

Portions of the product were alleged to be misbranded in that representations in the labeling that it was a prophylactic, would afford protection against disease, and was scientifically tested, were false and misleading.

Within the period from January 9, 1940, to May 1, 1942, no claimants having appeared, judgments of condemnation were entered and the product was ordered destroyed.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 426–540

PRODUCTS

[1] Prosecution contested.

[2] Contains instructions to the jury.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] Prosecution contested.

[2] Contains instructions to the jury.

[2] Contains instructions to the jury.

U. S. GOVERNMENT PRINTING OFFICE: 1942

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

541–600

DRUGS AND DEVICES

The cases reported herewith, commenced prior to June 30, 1940, were instituted in the United States District Courts by the United States attorneys acting upon reports submitted by direction of the Secretary of Agriculture; and those commenced on and after that date were similarly instituted upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

Washington, D. C., October 19, 1942.

CONTENTS

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

Nos. 541 to 545 report actions based on interstate shipments of Nature's Minerals (in tablet and in powder form) which, with the exception of one shipment, contained fluorine in amounts which might have rendered them injurious to health; and with the exception of the shipment described in No. 543, bore false and misleading therapeutic claims in the labeling.

541. Misbranding of Nature's Minerals Compound. U. S. v. Perry B. Smith and Thornton B. Smith (Nature's Mineral Co.). Pleas of guilty. Fines, $200. (F. D. C. No. 4178. Sample Nos. 26127–E, 26128–E, 26483–E, 26484–E, 35031–E, 35032–E.)

This product, in addition to being dangerous to health when used according to directions, because of its excessive fluorine content, also contained false and misleading claims in the labeling.

On October 27, 1941, the United States attorney for the Southern District of Indiana filed an information against Perry B. Smith and Thornton B. Smith, trading as Nature's Mineral Co., Indianapolis, Ind., alleging shipment from the State of Indiana into the States of Louisiana and Oregon, on or about August 26 and 29 and October 4, 1940, of quantities of Nature's Mineral Compound in powder and tablet form which was misbranded.

Analyses of samples of the article showed that it consisted essentially of compounds of calcium, magnesium, iron, and sodium, phosphates, carbonates, sulfates, chlorides, sulfur, and fluorine.

The article was alleged to be misbranded in that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, since it contained a poisonous substance, fluorine. The shipment of August 29, 1940, was alleged to be misbranded further in that statements appearing on the carton and bottle labels and the design in an accompanying circular of a hotel surrounded by palm trees underneath which appeared the words "Instead of $200.00 or $300.00 a Month," followed by an arrow showing a home underneath which were the words "You spend only $3.00 or 10¢ Per Day," and representations that the article could be used safely as an aid in supplying the minerals sometimes found deficient in the ordinary diet; that it would be efficacious in the treatment and alleviation of conditions for which a sojourn at a health resort is customarily prescribed; that the body normally requires the administration of alkaline substances to supplement those supplied by the usual and ordinary diet; that the effect of modern diet has been to modify the normal acid-alkali balance and, in cases of unbalance of the acid-alkali ratio, that the article would correct such unbalance; that it would restore health and prevent weakness; that the article was necessary to render the blood stream alkaline; that the ordinary diet is lacking in minerals and vitamins, which results in draining the system of its alkaline reserve; that it would correct the causes of flabby tissues and the effects of faulty elimination; that it would be efficacious to insure that the user would live to an advanced age without seeming old or losing his capacity to think or work; that it contained minerals which must be supplied specially; that it was needed for the proper functioning of important body processes; that the ordinary diet is deficient in minerals; that 99 percent of conditions of undernourishment are due to an acid condition and that it would enable every organ of the body to be nourished; that sickness, suffering, and shortness of life due to lack of minerals are general menaces; and that it would be efficacious to maintain or restore health, prevent loss of vitality, and remineralize the system, were false and misleading.

The remainder of the article was alleged to be misbranded further in that the statement appearing on the cartons and bottles, "Nature's Minerals * * * May be used as an aid in supplying in concrete form the minerals sometimes found deficient in the ordinary diet," were false and misleading since they represented that it could be used safely as an aid in supplying the minerals sometimes found deficient in the ordinary diet; whereas it could not be used safely for such purpose because of the presence of fluorine in deleterious amounts.

The article also was alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2996.

On January 31, 1942, the defendants having entered pleas of guilty, the court imposed fines of $150 against Perry B. Smith and $50 against Thornton B. Smith.

542. Misbranding of Nature's Minerals Compound. U. S. v. 28 Vials of Nature's Minerals Compound Tablets and 24 Boxes of Nature's Minerals Compound (and 2 other seizures of similar products). Default decrees of condemnation and destruction. (F. D. C. Nos. 3121, 3122, 3379, 3380. Sample Nos. 26483–E, 26484–E, 35031–E, 35032–E.)

On October 4 and November 26, 1940, the United States attorneys for the Southern District of Mississippi and the District of Oregon filed libels against 28 vials of Nature's Minerals Compound Tablets and 24 boxes of Nature's Minerals Compound (in powder form) at Bay St. Louis, Miss., and 12 bottles of Nature's Minerals Compound Tablets and 21 cartons of Nature's Minerals Compound (in powder form) at Portland, Oreg., alleging that the articles had been shipped on or about August 29 and on or about October 4, 1940, by Nature's Minerals Co. from Indianapolis, Ind.; and charging that they were misbranded.

Analyses of samples of the articles showed that they consisted essentially of compounds of calcium, magnesium, iron, and sodium, phosphates, carbonates, sulfates, chlorides, sulfur, and fluorine.

The articles were alleged to be misbranded (1) in that they would be dangerous to health when taken in accordance with the directions for use prescribed in the labeling; and (2) in that representations in the labeling [these representations are set forth in D. D. N. J. No. 541] were false and misleading since they would not be efficacious for such purposes.

They also were alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2997.

On January 7 and February 25, 1941, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

543. Misbranding of Nature's Minerals. U. S. v. 64 Bottles of Nature's Minerals Tablets and 15 Cartons and 19 Cartons of Nature's Minerals Powder. Default decree of condemnation and destruction. (F. D. C. No. 4819. Sample Nos. 32694–E to 32696–E, incl.)

On May 23, 1941, the United States attorney for the Southern District of California filed a libel against the above-named articles at Los Angeles, Calif., alleging that they had been shipped on or about September 19 and 26, 1940, and April 18, 1941, by Nature's Minerals Food Co. from Indianapolis, Ind.; and charging that they were misbranded.

The articles were alleged to be misbranded in that they would be dangerous to health when used in the dosage or with the frequency or duration prescribed in the labeling, namely, (carton containing the powder) "Directions—One round teaspoonful three times daily," or (bottles containing the tablets) "Average Directions: Take three tablets, three times daily before or after meals, for a reasonable time."

The articles were also alleged to be adulterated under the provisions of the law applicable to foods, as reported in F. N. J. No. 2998.

On June 17, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

544. Misbranding of Nature's Minerals. U. S. v. 40 12-Ounce Packages, 10 6-Ounce Packages, and 15 4-Ounce Packages of Nature's Minerals. Default decree of condemnation and destruction. (F. D. C. No. 4268. Sample Nos. 55461–E, 55462–E.)

On April 15, 1941, the United States attorney for the Western District of Washington filed a libel against the above-named product at Tacoma, Wash., alleging that it had been shipped in part by P. G. Jurich from Pasadena, Calif., on or about September 13, 1940, and January 9, 1941, and in part by Nature's Mineral Co. from Indianapolis, Ind., on or about September 17, 1940; and charging that it was misbranded.

Analyses of samples of the article showed that it consisted essentially of compounds of calcium, magnesium, iron, and sodium, phosphates, carbonates, sulfates, chlorides, sulfur, and fluorine.

The article was alleged to be misbranded in that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, which directed that ⅓ to 1 round teaspoonful be taken three times a day.

It was alleged to be misbranded further: (1) In that the statements, "Nature's Minerals may be used as an aid in supplying in concrete form the minerals sometimes found deficient in the ordinary diet. * * * Recommended as a scientific combination of minerals capable of being utilized by the different organs of the body. * * * Best results will be obtained by placing dry on the tongue," were false and misleading. (2) In that statements on display cards representing that it would be efficacious in the treatment or prevention of cancer, colds, hardening of the arteries, diabetes, stomach, blood, kidney, and bladder trouble, colitis, rheumatism, neuritis, and gallstone, and that by its use the purchaser would enjoy joyous and lasting health, were false and misleading since it would not be efficacious for such purposes. (3) In that representations in an accompanying circular [these representations are set forth in D. D. N. J. No. 541] were false and misleading since it would not be efficacious for such purposes.

It was alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2999.

On June 30, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

545. Misbranding of Nature's Minerals Compounds. U. S. v. 8 Bottles of Nature's Minerals Compounds Tablets, and 18 Cans and 20 Cans of Nature's Minerals Compounds Powder. Default decree of condemnation and destruction. (F. D. C. No. 4010. Sample Nos. 55434–E to 55436–E, incl.)

On March 21, 1941, the United States attorney for the Western District of Washington filed a libel against the above-named product at Seattle, Wash., alleging that it had been shipped on or about January 9 and 24, 1941, by P. G. Jurich from Pasadena, Calif.; and charging that it was misbranded.

Analyses of samples of the article showed that it consisted essentially of compounds of calcium, magnesium, iron, and sodium, phosphates, carbonates, sulfates, chlorides, sulfur, and fluorine (3,600 parts per million in 8 bottles, 4,320 parts per million in 18 cans, and but a trace in 20 cans).

Portions of the article (8 bottles and 18 cans) were alleged to be misbranded in that it would be dangerous to health when used in the dosage or with the

frequency or duration prescribed in the labeling, which directed that 8 tablets or 1 teaspoonful of the powder be taken three times daily.

The article was alleged to be misbranded further: (1) In that the following statements (8 bottles) "Nature's Minerals * * * May be used as an aid in supplying in concrete form the minerals sometimes found deficient in the ordinary diet"; (18 cans) "Nature's Minerals * * * 'Nature's Minerals' is an organic and inorganic combination representing mineral constituents which occur in the human body. * * * Best results will be obtained by placing dry on the tongue * * * May be used as an aid in supplying in concrete form the minerals sometimes found deficient in the ordinary diet"; and (20 cans) "Nature s Minerals * * * Best results will be obtained by placing dry on tongue," were false and misleading. (2) In that statements in accompanying display cards and circulars which represented that it would be efficacious in the treatment of arthritis, neuritis, sciatica, indigestion, diabetes, colitis, gastritis, skin and nervous ailments; that it would remineralize the system and rebuild the glands; that it would insure the user that he would live to an advanced age without seeming old or losing his capacity to think or work; that it would drain the acids from the tissue cells; that it would enter directly into the blood and would be carried to every gland, organ, nerve and muscular cell and supply any element lacking or deficient; that it would banish acid conditions of the stomach and help digestion; that it would have a purifying action on the blood and aid in the elimination of waste matter; that it would "Bring the great health Resorts right into your own home" and would alleviate conditions for which a sojourn at such resorts is customarily prescribed; that it would produce fine results in the treatment of hives, goiter, diabetes, colitis, rheumatism, high blood pressure, and liver, stomach, kidney and bladder troubles; that its use would prevent the development of goiter, skin disease, neuritis, obesity, rickets, anemia, weakness, asthma, stomach trouble, eczema, subnormal growth, nervous exhaustion, rheumatism, kidney and bladder trouble, constipation, acidosis and heart disorders, arthritis, blood disorders, high blood pressure, stomach ulcers, diabetes, bladder and kidney ulcers, tumors, mental and physical exhaustion, and premature old age; and that users might reasonably expect the article to produce normal bone development, thyroid health and vitality, improved metabolism, red blooded cells, increased vitality, good teeth, alkalinity, normal cell activity, sturdy bones, clear thought, good digestion, increased gastric juices, improved heart and liver action, improved body tissue, clear skin, steady nerves, better health and vitality and to dissolve calcium in arthritis, purify the blood, nourish every gland and organ, eliminate toxic poisons and acids, improve digestion and prevent fermentation, were false and misleading since it would not be efficacious for such purposes.

It also was alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 3000.

On June 23, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

546. Misbranding of Breatheasy kits and inhalant. U. S. v. 2 Breatheasy Kits, 12 Bottles, 2 Bottles, and 14 Bottles of Inhalant for use in Breatheasy Nebulizer. Default decree of condemnation and destruction. (F. D. C. No. 4627. Sample Nos. 60707–E, 60708–E.)

This product would be dangerous to health when used according to directions, and the labeling bore false and misleading therapeutic claims and also failed to comply with other requirements of the law.

On May 5, 1941, the United States attorney for the District of Massachusetts filed a libel against 2 Breatheasy kits and 12 1-fluid-ounce bottles and 16 ½-fluid-ounce bottles of inhalant at New Bedford, Mass., alleging that the article had been shipped on or about November 27, 1940, and March 17 and April 26, 1941, by Breatheasy Distributors, Inc., from Seattle, Wash.; and charging that it was misbranded.

Examination of the inhalant showed that it had the activity of 3 percent synthetic racemic epinephrine hydrochloride.

The article was alleged to be misbranded (1) in that it would be dangerous to health when used in the dosage or with the frequency and duration prescribed, recommended, or suggested on the bottle label and in an accompanying booklet; (2) in that statements in the accompanying booklet which created the impression that it was a safe, appropriate, and efficacious treatment for asthma, hay fever, dermatitis, eczema, chronic bronchitis, and head colds, when used by the ordinary individual under customary conditions of purchase and use, were false and misleading since it was not a safe, appropriate, and effective treatment for such ail-

ments when so used; (3) in that the carton label failed to bear the common or usual names of the active ingredients; (4) in that the carton label failed to bear the name and place of business of the manufacturer, packer, or distributor; and (5) in that the carton label failed to bear a statement of the quantity of contents.

On July 8, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

547. Misbranding of Special Formula Tablets and McNeal's Laxative Cold Tablets. U. S. v. 88,020 Tablets in containers labeled "Special Formula Tablets—Mono. 'L'" and 41 Dozen Boxes of similar tablets labeled "McNeal's Laxative Cold Tablets." Consent decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 4037. Sample Nos. 28397-E, 28398-E.)

These tablets were of identical composition. Those in boxes labeled "McNeal's Laxative Cold Tablets" would have been dangerous to health when used according to directions on the label; they also contained false and misleading therapeutic claims. These tablets and the loose ones in the large container failed to bear adequate directions for use and adequate warning statements. The label for the loose tablets also failed to bear the required ingredient statement.

On March 24, 1941, the United States attorney for the District of Maryland filed a libel against the above-named product at Baltimore, Md., alleging that it had been shipped from Buffalo, N. Y., on or about December 16, 1940, by Arner Co., Inc.; and charging that it was misbranded.

Analysis of a sample of the article showed that each tablet contained acetanilid (approximately 1 grain), quinine sulfate (approximately 0.38 grain), a laxative plant drug, and a small amount of atropine.

McNeal's Laxative Cold Tablets were alleged to be misbranded in that they would have been dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, "Directions;—Usual dose. 2 tablets just after meals & at bedtime. Delicate persons may take 1. When relieved take half dose for day or two. Children over 10, ½ adult dose. Limit 4 doses—24 hrs." They were alleged to be misbranded further in that the following statements appearing on the label were false and misleading, "Laxative Cold Tablets Relief for Common Colds * * * A Preparation for Colds * * * The 2nd or 3rd dose should relieve the Cold * * * partly as a result of bowel movement which should occur in 10 hours after taking," since they represented that the article would be efficacious for the purposes recommended; whereas it would not be efficacious for such purposes. The product in both types of containers was alleged to be misbranded in that the labeling did not bear adequate directions for use, and in that the labeling did not bear such adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users. The Special Formula Tablets were alleged to be misbranded further in that the label did not bear the common or usual names of the active ingredients or a statement of the quantities or proportions of acetanilid and atropine contained therein.

On May 12, 1941, Kent Drug Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be relabeled under the supervision of the Federal Security Agency (Food and Drug Administration).

548. Misbranding of Tabknoll Three Bromides Effervescent. U. S. v. 10 Dozen Bottles of Tabknoll Three Bromides Effervescent. Default decree of condemnation and destruction. (F. D. C. No. 3918. Sample No. 34893-E.)

This product contained ammonium, potassium, and sodium bromides, and would be dangerous to health when used as recommended in the labeling. Its labeling also failed to bear adequate directions for use and adequate warnings against its use where such use might be dangerous to health.

On March 6, 1941, the United States attorney for the District of New Jersey filed a libel against 10 dozen bottles of Tabknoll Three Bromides Effervescent at Newark, N. J., alleging that the article had been shipped in interstate commerce on or about January 6, 1941, by H. G. Knoll & Co., Inc., from New York, N. Y.; and charging that it was misbranded.

The article was alleged to be misbranded (1) in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in the labeling, namely, (bottle and carton) "Adults, one to two tablets, dissolved in half a glass of water; or as ordered

by the physician."; (2) in that its labeling failed to bear adequate directions for use; and (3) in that its labeling failed to bear adequate warnings against use where such use might be dangerous to health or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users.

On September 4, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

549. Misbranding of Dr. Whitehall's Compound Tablets. U. S. v. 642 Boxes of Dr. Whitehall's Compound Tablets. Default decree of forfeiture and destruction. (F. D. C. No. 3681. Sample No. 38625–E.)

On or about January 17, 1941, the United States attorney for the Western District of Wisconsin filed a libel against 642 boxes of Dr. Whitehall's Compound Tablets at La Crosse, Wis., alleging that the article had been shipped on or about November 27 and December 3, 1940, by the Dr. Whitehall Megrimine Co. from South Bend, Ind; and charging that it was misbranded. It was labeled in part: (Box, carton, and circular) "For Mitigating the Distress and Discomfort of Minor Muscular Aches and Pains," and (circular only) "If you are subject to attacks on change of weather or exposure, one tablet taken in time will often prevent distress and discomfort."

Analysis of a sample of the article showed that it contained acetanilid, sodium salicylate, and plant material.

The article was alleged to be misbranded (1) in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, since when used in the dosage and with the frequency or duration prescribed, recommended, and suggested, such use might cause serious blood disturbances, anemia, collapse, and a dependence on the drug; (2) in that the labeling failed to bear adequate directions for use since it did not provide for a limit as to the duration or frequency of administration; (3) in that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users; and (4) in that the labeling was false and misleading since it created the impression that the article constituted an appropriate treatment for the conditions described therein; whereas it was not a safe and appropriate remedy but was a dangerous drug, and the label failed to reveal the material fact that its use in accordance with the directions might cause serious blood disturbances, anemia, collapse, or a dependence on the drug.

On March 17, 1941, no claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

550. Adulteration and misbranding of Zerbst's Capsules. U. S. v. 139 Packages of Zerbst's Capsules [25-cent size] and 23 Packages of Zerbst's Capsules [50-cent size]. Default decree of condemnation and destruction. (F. D. C. No. 4970. Sample No. 60418–E.)

These products would be potentially dangerous to health when used according to directions and they failed to bear adequate directions for use and warning statements. The capsules in the 25-cent-sized packages contained more acetanilid than the amount stated on the label, and those in the 50-cent-sized packages bore false and misleading therapeutic claims and failed to bear the required ingredient and quantity of contents statements.

On June 24, 1941, the United States attorney for the District of Oregon filed a libel against the above-named products at Portland, Oreg., alleging that they had been shipped on or about January 20, 1941, by the Zerbst Pharmacal Co. from St. Joseph, Mo.; and charging that a portion were adulterated and misbranded and that the remainder were misbranded.

Analyses of samples of the capsules showed that those in the 25-cent packages contained acetanilid (1¼ grains per capsule), together with caffeine, resinous material, camphor, capsicum, aloin, and asafoetida; and that those in the 50-cent packages contained acetanilid (2⅛ grains per capsule), together with a laxative plant drug.

The capsules in the 25-cent packages were alleged to be adulterated in that their strength differed from that which they purported or were represented to possess, namely, "Each Capsule contains as active ingredients, Acetanilid 1 Grain"; whereas they contained materially more than 1 grain of acetanilid.

The capsules in the packages of both sizes were alleged to be misbranded: (1) In that they were dangerous to health when used according to the directions

on the label. (2) In that the directions for use, namely, "Adults—To allay the discomfort in breaking up a common head cold, simple headache, or neuralgia, take one capsule every half hour until three are taken [25-cent size] then one capsule in two or three hours until three more capsules are taken. Children—12 years old, one capsule repeated in three hours [50-cent size] then one every 2 or 3 hours as may be desired. Children—5 to 10 years old, one-half to one capsule, repeated in three hours if necessary," were inappropriate for articles of such composition because of their indefiniteness and because they provided amounts of acetanilid which might prove harmful to the user and were therefore inadequate. (3) In that the labels failed to bear adequate warnings against their use by children or in those pathological conditions where their use might be dangerous to health and against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users, since there was no warning against their use by children nor against use in the presence of symptoms of appendicitis, nor with reference to the deleterious effects of acetanilid in causing serious blood disturbances, nor against frequent or continued use which might result in dependence upon the drug.

The capsules in the 50-cent-sized packages were alleged to be misbranded further (1) in that the statements (box label) "Should give a free evacuation which is very important in breaking up a cold" and (circular) "For relieving common head colds" were false and misleading since they would not break up a cold nor otherwise favorably influence the course of a head cold; (2) in that the label failed to bear the common or usual name of each active ingredient since, of the several active ingredients present, only acetanilid was mentioned on the label; and (3) in that the label did not bear a statement of the quantity of contents of the retail package.

On August 27, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR DIRECTIONS FOR USE OR ADEQUATE WARNING STATEMENTS[1]

551. Adulteration and misbranding of Sunshine Brand Powders. U. S. v. Frank W. Lavoine (Lavoine Drug Co.). Plea of guilty. Fine, $25. (F. D. C. No. 4113. Sample No. 36160-E.)

These powders contained acetanilid in excess of the amount declared on the label. The labeling failed to bear such warnings as are necessary for the protection of users and it also failed to bear a statement of the quantity of contents.

On July 29, 1941, the United States attorney for the District of Massachusetts filed an information against Frank W. Lavoine, trading as the Lavoine Drug Co., Worcester, Mass., alleging shipment on or about October 5, 1940, from the State of Massachusetts into the State of Maine of a quantity of Sunshine Brand Powders which were adulterated and misbranded.

Adulteration was alleged in that the strength of the article differed from that which it purported and was represented to possess since each powder purported and was represented to contain 2 grains of acetanilid; whereas each powder contained approximately 3.158 grains of acetanilid.

Misbranding was alleged (1) in that the labeling did not bear adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users, since frequent or continued use might cause serious blood disturbances, anemia, or collapse; (2) in that it might be dangerous if administered to children, and its labeling did not bear a warning that it should not be given to children; (3) in that the statement "Each powder contains 2 grains Acetanilid," borne on each of the boxes and envelopes, was false and misleading; and (4) in that it was in package form and did not bear a label containing an accurate statement of the quantity of the contents in terms of weight or numerical count.

On December 15, 1941, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of $25.

552. Misbranding of Floracubes. U. S. v. Eugene H. Hunter (Floracube Co.). Plea of nolo contendere. Imposition of sentence suspended and defendant placed on probation for 5 years. (F. D. C. No. 2899. Sample No. 7356-E.)

This product was labeled to indicate that it derived its physiological activity in important respects by means of its lubrication, bulk, alkaline, and germicidal

[1] See also Nos. 547-550.

qualities; whereas it derived its physiological activity principally from the ingredient phenolphthalein.

On March 28, 1941, the United States attorney for the Southern District of California filed an information against Eugene H. Hunter, trading as Floracube Co., Los Angeles, Calif., alleging shipment on or about March 9, 1940, from the State of California into the State of Arizona of quantities of Floracubes that were misbranded.

The article was alleged to be misbranded in that the statements "Floracubes * * * contain certain lubrication, bulk, alkaline, and germicidal qualities, and are non-irritating in action. May be used over a long period of time. * * * Floracubes * * * contain per average dose (1-6 box) less than 2 grains each of calcium carbonate, sodium bicarbonate, chlorides, podophyllum, magnesium, phenolphthalein, oil of juniper, boron, buchu, sodium benzoate, cascara, iron and dextrin. Also mineral oil and jelly, agar and celluloses, sugar, artificial color and flavor, combined with free oxygen, hydrogen and Ultra Violet. The above ingredients are combined with water under a special process to change their form and action to meet the requirements of Floracubes. * * * (Additional ingredients present, less 1 Gr.) Manganese, Aloin, nitrates, florides, sassafras, sulphates, calcium and silica," borne on the carton, were false and misleading since they represented that the article derived its physiological activity in important respects by reason of its lubrication, bulk, alkaline, and germicidal qualities; that it was nonirritating in action and might safely be used over a long period of time; and that it contained the ingredients listed in significant amounts and that these ingredients were combined with water under a special process which changed their form and action; whereas it derived its physiological activity practically, if not entirely, from the ingredient phenolphthalein, which is irritating; it was not germicidal, and could not be used over a long period of time without risk of injury; and it did not contain the ingredients listed in significant amounts, since it contained no appreciable amount, if any, of the ingredients iron, boron, manganese, fluorine, sodium bicarbonate, calcium as calcium carbonate, or sodium benzoate, and the ingredients were not combined with water under a special process which changed their form and action. It was alleged to be misbranded further in that it did not bear a label containing the name and place of business of the manufacturer, packer, or distributor, nor an accurate statement of the quantity of the contents prominently placed thereon with such conspicuousness, as compared with other words, statements, designs, or devices in the labeling, as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. It was alleged to be misbranded further in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient, since the ingredients listed in the labeling were in large part inert and the list did not indicate that phenolphthalein was the only important active ingredient. It was alleged to be misbranded further in that its labeling failed to bear adequate directions for use, and such adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since the labeling did not inform purchasers that the use of the article in cases of abdominal pain, nausea, vomiting, or other symptoms of appendicitis might result in serious injury, and that frequent or continuous use might result in dependence upon laxatives.

On August 25, 1941, the defendant entered a plea of nolo contendere, and the court ordered that imposition of sentence be suspended and that the defendant be placed on probation for a period of 5 years.

553. Misbranding of Mackenzie Cold and Grippe Tablets. U. S. v. 100 Packages of Mackenzie Cold and Grippe Tablets. Default decree of condemnation and destruction. (F. D. C. No. 4876. Sample No. 60255–E.)

These tablets had been repackaged after shipment and after such repackaging, in addition to failure to bear adequate warning statements, the labeling bore false and misleading statements regarding their therapeutic efficacy and the amount of acetanilid that they contained. The tablets also were deceptively packaged since approximately 30 percent of the upper space in the carton was empty.

On June 10, 1941, the United States attorney for the Western District of Washington filed a libel against the above-named product at Seattle, Wash., alleging that it had been shipped on or about March 19, 1941, by C. E. Jamieson & Co. from Detroit, Mich., and that subsequently it had been repackaged by Guy, Inc., at Seattle, Wash.; and charging that it was misbranded.

Analyses of samples of the article showed that it consisted essentially of acetanilid (0.94 grain per tablet), caffeine, aloin, atropine sulfate, and capsicum.

The article was alleged to be misbranded: (1) In that its labeling failed to bear such adequate warnings as are necessary for the protection of users, against use in those pathological conditions or by children, where its use might be dangerous to health, since it might be dangerous to health when used by persons suffering from nausea, vomiting, abdominal pain, or other symptoms of appendicitis, or by children; and in that the labeling failed to bear adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users, since frequent or continued use of this acetanilid-containing preparation might cause serious blood disturbances, anemia, or collapse, and since its use might result in dependence on a laxative. (2) In that the statements on the label, "Cold and Grippe Tablets Excellent for a feverish condition, coryza, hay fever, rhinitis, grippe, aching muscles, colds, influenza * * * acetanilid 2 gr.," were false and misleading since it was not an adequate treatment for the conditions named and since each tablet did not contain 2 grains of acetanilid. (3) In that its package container was so filled as to be misleading since the bottle was materially shorter than the package [carton].

On September 29, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

554. Misbranding of "Doctor's Daughter" Tablets (and Dr. Wilbur's Laxative Tablets). U. S. v. 5½ Dozen Packages of "Doctor's Daughter" Tablets. Default decree of condemnation and destruction. (F. D. C. No. 4779. Sample No. 56820–E.)

Each package of this product contained 50 white tablets wrapped in wax paper and an envelope labeled "Dr. Wilbur's Laxative Tablets," which contained 25 pink tablets. The labeling, in addition to failure to bear adequate warning statements, also failed to bear the required ingredient and quantity of contents statements.

On May 16, 1941, the United States attorney for the Southern District of New York filed a libel against 5½ dozen packages of "Doctor's Daughter" Tablets at New York, N. Y., alleging that the article had been shipped by Dr. John Wilbur Daughter Co. from Westerly, R. I., on or about April 16, 1941; and charging that it was misbranded.

Analyses of samples showed that the white tablets consisted essentially of calcium carbonate, sodium carbonate, and sodium bicarbonate; and that the pink tablets consisted essentially of belladonna alkaloids including atropine, and laxative plant drugs.

The article was alleged to be misbranded: (1) In that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, since the labeling did not warn that frequent or continued use might result in dependence upon laxatives and that the article should not be taken when suffering from nausea, vomiting, abdominal pain, or other symptoms of appendicitis. (2) In that the carton label did not bear the common or usual names of the active ingredients nor a statement of the quantity or proportion of belladonna alkaloids contained in the laxative tablets. (3) In that the envelope containing the laxative tablets did not bear a statement of the quantity or proportion of belladonna alkaloids nor did it bear the common or usual names of all the active ingredients, since "Exl" and "phodophyllui" did not inform that extract and podophyllum were meant. (4) In that the carton label did not bear an accurate statement of the quantity of contents, since no reference was made to the envelope containing the 25 laxative tablets.

On July 3, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

555. Misbranding of Starr's Wonderful M. L. & K. Pills. U. S. v. 8 Dozen Packages of Starr's Wonderful M. L. & K. Pills. Default decree of condemnation and destruction. (F. D. C. No. 4877. Sample No. 31996–E.)

The label of this product, in addition to failure to bear adequate directions for use and warning statements, also failed to bear the required ingredient and quantity of contents statements. Furthermore, the label bore false and misleading therapeutic claims.

On June 10, 1941, the United States attorney for the Northern District of Illinois filed a libel against the above-named product at Chicago, Ill., alleging

that it had been shipped on or about April 1, 1941, by the Starr Medicine Co. from San Francisco, Calif.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of extracts of plant drugs including laxative plant drugs, coated with calcium carbonate.

The article was alleged to be misbranded: (1) In that the label failed to bear adequate directions for use since the dosage given was not appropriate for a laxative, namely, "Dose—1 to 2 at Bedtime." (2) In that the label failed to bear adequate warnings in such manner and form as were necessary for the protection of users, against use in those pathological conditions where its use might be dangerous to health, and against unsafe duration of administration, since the labeling failed to bear warnings that it was not to be taken when suffering from nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and that continued use might result in dependence upon a laxative. (3) In that the following statements, appearing on the label, were false and misleading since it contained no ingredients which would constitute treatment for the conditions quoted: "Courage Manhood Nature Used In Weak Back, Liver, Kidney Complaints, Biliousness, * * * Cold, Fever, Headaches, Indigestion." (4) In that the label failed to bear the common or usual names of the active ingredients. (5) In that the label did not bear an accurate statement of the quantity of contents.

On August 25, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

556. Misbranding of T. S. B. Saline. U. S. v. 53 Cards, to each of which were attached 12 Envelopes, 27 Dozen 2½-Ounce Bottles, and 20 Dozen 8-Ounce Bottles of T. S. B. Saline. Default decree of condemnation and destruction. (F. D. C. No. 4753. Sample No. 42377–E.)

The labeling of this product failed to bear adequate warning statements and directions for use, it contained false and misleading therapeutic claims, and the quantity of contents statement "3 Dram" on the envelopes was inaccurate since the contents varied from 3.97 to 4.82 drams, and on the bottle label it was inconspicuously placed.

On May 13, 1941, the United States attorney for the Western District of Pennsylvania filed a libel against the above-named product at Erie, Pa., alleging that it had been shipped on or about March 18, 1941, by T. S. Burns & Boys Co. from Buffalo, N. Y.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of a mixture of partially dehydrated Epsom salt and Glauber's salt, with traces of magnesium carbonate and sodium chloride.

The article was alleged to be misbranded: (1) In that the labeling failed to bear adequate directions for use, since the statement appearing on the bottle labels, "Directions: Children According to age, use one-half to one teaspoonful, dissolved in water," did not set forth the dosage for different age groups and such statement did not indicate that the article would be dangerous to health when used by very young children. (2) In that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users, since the envelopes carried no warning with reference to avoidance of the article in abdominal pain, nausea, vomiting, and other symptoms of appendicitis, nor against frequent or continued use when such use might result in dependence on the use of a cathartic to move the bowels; the bottle labeling carried no warning against frequent or continued use and the warning to avoid laxatives in case of severe abdominal pains was not adequate to warn the purchaser that laxatives should not be used in case of abdominal pain, nausea, and vomiting, which might be symptoms of appendicitis. (3) In that statements appearing in the labeling, which represented that it would be efficacious as a laxative and intestinal cleanser, that it would be efficacious in the treatment of rheumatism, constipation, indigestion, colds, skin rash, biliousness, and many conditions arising from faulty elimination; and that it would be helpful to help Nature help itself, were false and misleading since it would not be efficacious for such purposes. (4) In that magnesium carbonate ("Magnes. Carb."), listed on all the labels as an active ingredient, was not an active ingredient since it was present in traces only. (5) In that the labels failed to bear the common or usual name of each ingredient since "Soda. Sulph.," on the envelope and 2½-ounce bottle label, was not the common or usual name for sodium sulfate; the term "Magnes. Sulph.," appearing on the envelopes and the 2½-ounce bottle label, and the term "Mag-

nesium Sulphate," appearing on the 8-ounce bottle label, were not the common or usual name for Epsom salt. (6) In that the envelopes failed to bear an accurate statement of the quantity of contents since the statement "3 Dram" was not an accurate statement of the quantity of contents of the package. (7) In that the declaration of quantity of contents on the bottles was not prominently placed thereon with such conspicuousness (as compared with other words, statements, and designs in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the statement did not appear upon the principal display panels of the labels.

On June 13, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

557. Misbranding of Velpaus Pills. U. S. v. 4½ Dozen Packages of Velpaus Pills. Default decree of condemnation and destruction. (F. D. C. No. 5106. Sample No. 29500-E.)

This product, in addition to failure to bear adequate directions for use and warning statements, bore false and misleading therapeutic claims.

On July 9, 1941, the United States attorney for the Southern District of Ohio filed a libel against the above-named product at Columbus, Ohio, alleging that it had been shipped on or about June 2, 1941, by F. W. Briggs & Co. from Buffalo, N. Y.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of aloes, ferrous sulfate, myrrh, and starch, together with volatile oils including savin oil, and coated with sugar and chalk.

The article was alleged to be misbranded: (1) In that it failed to bear adequate directions for use since those given on the carton and in the circular were not appropriate for the administration of a laxative. (2) In that the labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, since the warning which was printed on the circular failed to convey the information that this particular article should not be taken when suffering from nausea, abdominal pain, vomiting, or other symptoms of appendicitis and that frequent or continued use might result in dependence upon a laxative. (3) In that the following statements, "Two days before the expected menstruation take one pill before meals and at bedtime. Bathe the feet and lower legs in hot mustard water. Drink freely of hot ginger tea. Cover up and keep warm. This preparation may be dangerous and should be used under medical supervision," were false and misleading since it did not constitute a treatment for delayed menstruation and would not be effective when used under medical supervision. (4) In that the following statements, "In constipation cases we recommend a mild cathartic to keep the bowels open and easy. Exercise in the open air is helpful, keeping the body and feet warm. Not for habitual use. In case of nausea, abdominal pain, or vomiting, avoid the use of all laxatives and cathartics," were false and misleading since they failed to reveal that it was a laxative and they created the impression that some other product should be taken if a laxative action were desired.

On October 10, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

558. Adulteration and misbranding of vitamin B complex tablets. U. S. v. 2,750 Special Formula No. 8558 Tablets and 717 Bottles and 65 Envelopes of Vitamin B Laxative. Default decree of condemnation and destruction. (F. D. C. No. 4873. Sample Nos. 11178-E to 11180-E, incl., 11401-E to 11403-E, incl.)

These tablets represented a portion of a bulk shipment of tablets in 2 drums labeled in part "Special Formula No. 8558," the greater portion of which had been repackaged and relabeled by the consignee after shipment. In addition to failure to bear adequate directions for use and warning statements, the labeling of these tablets bore false and misleading statements regarding their composition and therapeutic efficacy and also failed to bear the common or usual names of their active ingredients.

On June 5, 1941, the United States attorney for the Western District of Texas filed a libel against 2,750 Special Formula No. 8558 Tablets, 737 bottles and 65 envelopes containing a total of 45,521 tablets at San Antonio, Tex., alleging that the article had been introduced in interstate commerce on or about February 1, 1941, at Bristol, Tenn., and that it was then in the possession of the Medical

Specialty Co. at San Antonio, Tex.; and charging that it was adulterated and misbranded.

The article was labeled in part: (Repackaged portion, bottles) "500 [or "100" or "50"] Compressed Tablets 'Vitalax' non habit forming. Vitamin B Laxative from yeast concentrate with Sodium Glyco and Taurocholate. Water soluble vitamin B complex from fresh dehydrated Brewer's yeast Stimulates liver function. Produces abundant flow of bile necessary for normal digestion and proper elimination without the use of habit forming cathartic drugs Suggested Dose 1 to 3 tablets daily * * * Each Tablet Contains: Sodium Taurocholate 0.0325 Gm. Sodium Glycocholate 0.0325 Gm. Yeast Concentrate 0.026 Gm."; (portion of bottles and drum containing tablets not repackaged) "12 Compressed Tablets 'Vitalax' Each Tablet Contains Sodium Taurocholate 0.015 Gm. Sodium Glycocholate 0.015 Gm. Yeast Concentrate 0.025 Gm. * * * Vitamin B Laxative Concentrate with Bile Salts Compound Water soluble Vitamin B Complex from Fresh Dehydrated Brewer's Yeast"; (envelopes) "5 Compressed Tablets 'Vitalax' Non-Habit Forming For Faulty Elimination Vitamin B Laxative from yeast concentrate with Sodium Glyco and Taurocholate. * * * it tends to tone the digestive tract. Produces abundant flow of bile of physiologically normal composition. Stimulates peristaltic action without the use of habit-forming cathartic drugs. Suggested dosage: 1 to 3 tablets daily."

Analyses of samples of the article showed that it contained phenolphthalein (approximately 1 grain per tablet) together with extracts of yeast and bile.

The article was alleged to be adulterated in that a substance, phenolphthalein, had been substituted in part therefor.

It was alleged to be misbranded: (1) In that its labeling failed to bear adequate directions for use since (in the case of the tablets in original container) the label bore no directions for use, and (in the case of the repackaged tablets) the statement "Suggested dose 1 to 3 tablets daily" was not a suitable or appropriate direction for the use of laxative tablets of its composition. (2) In that the labeling failed to bear adequate warnings against use by children where its use might be dangerous to health; against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, since it failed to bear adequate warnings against the potential danger of establishing dependence upon laxatives to move the bowels; it failed to bear a warning to discontinue its use on the appearance of a skin rash; and, in the case of the repackaged portion, it failed to bear a warning against its use in the presence of abdominal pain, nausea, vomiting, or other symptoms of appendicitis. (3) In that the statements on the labels were false and misleading with respect to its composition, since they did not reveal the material fact that the tablets contained phenolphthalein, a coal-tax laxative drug. (4) (Repackaged portion only) In that the designations, "Vitalax" and "Vitamin B Laxative," on the labels were false and misleading since they gave the impression that the laxative property of the tablets was due to their vitamin or vitamin B content; whereas such laxative property was not due to their vitamin or vitamin B content but to their phenolphthalein content. (5) (Portion repackaged in bottles only except those containing 12 tablets) In that the statements on labels, "Stimulates liver function" and "Produces abundant flow of bile necessary for normal digestion and proper elimination without the use of habit forming cathartic drugs," were false and misleading since it was not efficacious for such purposes and did contain a habit-forming cathartic drug, namely, phenolphthalein. (6) (Portion repackaged in envelopes) In that the statements on the label, "It tends to tone the digestive tract. Produces abundant flow of bile of physiologically normal composition. Stimulates peristaltic action without the use of habit-forming cathartic drugs," were false and misleading since it would not tone the digestive tract, would not produce an abundant flow of bile of physiologically normal composition, and would stimulate peristaltic action because of its content of a habit-forming cathartic drug, phenolphthalein. (7) (Repackaged portion only, except bottles containing 12 tablets) In that the statement "Non Habit Forming" on the labels was false and misleading since its frequent or continued use might result in the establishment of the laxative habit. (8) In that the labeling failed to bear the common or usual name of each of its active ingredients, since it did not mention phenolphthalein, an active ingredient. (9) (Repackaged portion only) In that bile extract was an active ingredient but was not specified on the label by its common or usual name, since neither "Sodium Taurocholate," "Sodium Glycocholate," nor (in the case of the bottles containing 12 tablets) "Bile Salts Compound," is the common or usual name of bile extract.

On August 27, 1941, the Medical Specialty Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be relabeled under the supervision of the Food and Drug Administration.

559. Misbranding of Cravex. U. S. v. 42 Packages of Cravex. Default decree of condemnation and destruction. (F. D. C. No. 4723. Sample No. 11249–E.)

In addition to failure to bear adequate directions for use in the labeling, this product was misbranded in that the name "Cravex" in the labeling would falsely imply that it constituted an adequate treatment for alcoholism.

On May 8, 1941, the United States attorney for the Southern District of Texas filed a libel against 42 packages of Cravex at Houston, Tex., alleging that it had been shipped on or about February 21, 1941, by Plant Products Co., Inc., from Burbank, Calif.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of calcium and manganese compounds, including phosphates, caffeine, and milk sugar.

The article was alleged to be misbranded (1) in that the labeling did not bear adequate directions for use, since the directions appearing on the package were not adequate for the treatment of alcoholism, a disease for which it was advertised; and (2) in that the labeling was false and misleading since the name "Cravex" was interpreted by advertising to mean treatment for craving for alcohol, and it did not constitute adequate treatment for such condition.

On June 17, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS SEIZED BECAUSE OF CONTAMINATION WITH FILTH

560. Adulteration of bonita livers. U. S. v. 122 Cans of Bonita Livers. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 5417. Sample No. 63538–E.)

Portions of this product were found to be decomposed and putrid.

On August 20, 1941, the United States attorney for the Western District of Washington filed a libel against 122 5-gallon cans of bonita livers at Seattle, Wash., alleging that the article had been shipped by Parke, Davis & Co. from San Francisco, Calif., on or about July 30, 1941; and charging that it was adulterated in that it consisted in whole or in part of a filthy substance.

It also was alleged to be adulterated under the provisions of the law applicable to foods, as reported in F. N. J. No. 2093.

On September 10, 1941, Parke, Davis & Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be brought into compliance with the law under the supervision of the Food and Drug Administration. Subsequently all the cans containing the product were inspected and those found to be unfit were destroyed.

561. Adulteration of crude drugs. U. S. v. 2 Barrels of "Broken Alex Senna Lvs Pumpkin Seed American Wormseed Anise Seed." Default decree of condemnation and destruction. (F. D. C. No. 5673. Sample No. 48086–E.)

This product was contaminated with insect fragments and excreta.

On September 11, 1941, the United States attorney for the Northern District of Georgia filed a libel against 2 barrels of the above-named product at Atlanta, Ga., alleging that the article had been shipped in interstate commerce on or about January 28, 1941, by R. Hillier's Son Corporation from New York, N. Y.; and charging that it was adulterated in that it consisted in part of a filthy substance.

On October 7, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

562. Adulteration of ginger root. U. S. v. 47 Bags of Ginger. Consent decree of condemnation. Product ordered released under bond to be converted into an inedible product. (F. D. C. No. 6356. Sample No. 67714–E.)

Examination showed that this product contained worm holes and further evidence of insect infestation.

On December 4, 1941, the United States attorney for the Western District of Tennessee filed a libel against 47 bags containing 5,229 pounds of ginger at Memphis, Tenn., alleging that the article had been shipped in interstate commerce on or about September 6, 1940, by J. R. Watkins Co. from Newark, N. J.; and charging that it was adulterated in that it consisted in whole or in part of a filthy, putrid, or decomposed substance.

It also was alleged to be adulterated under the provisions of the law applicable to foods, as reported in F. N. J. No. 2985.

On February 27, 1942, J. R. Watkins Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be converted under the supervision of the Food and Drug Administration into an inedible product.

563. Adulteration of miscellaneous drugs. U. S. v. A Certain Quantity of Drugs. Consent decree of condemnation. Products ordered released under bond for segregation and relabeling of fit portions. (F. D. C. No. 4214. Sample Nos. 56786-E to 56794-E, incl.)

This case was based on a shipment of salvaged smoke- and water-damaged goods which included various drugs such as "patent medicines," pharmaceuticals used in the filling of prescriptions, surgical dressings, and vitamin capsules.

On April 15, 1941, the United States attorney for the Southern District of New York filed a libel against 284 cartons of miscellaneous merchandise, including a certain quantity of drugs, at New York, N. Y., alleging that the articles had been shipped on or about February 26 and 28, 1941, by Curtis & Travis from Harrisburg, Pa.; and charging that the drugs were adulterated in that they consisted in whole or in part of filthy substances, and in that they had been held under insanitary conditions whereby they might have become contaminated with filth.

The libel also covered quantities of foods and cosmetics that were adulterated, as reported in F. N. J. No. 2825 and in notices of judgment on cosmetics.

On April 30, 1941, Gibbs Peoples Drug Service Co., Harrisburg, Pa., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the products were ordered released under bond conditioned that the fit portions be segregated and relabeled in compliance with the law.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH OFFICIAL OR OWN STANDARDS[2]

564. Adulteration of aromatic spirit of ammonia, sweet spirit of niter, and camphorated oil; and misbranding of Dewee's Carminative. U. S. v. Owens & Minor Drug Co., Inc. Plea of guilty. Fine, $50. (F. D. C. No. 2965. Sample Nos. 28853-E, 28855-E, 28856-E, 28858-E.)

This case involved 3 drugs which differed from the requirements of the United States Pharmacopoeia; also a shipment of Dewee's Carminative which contained opium and which was not labeled with the warning that it might be habit-forming.

On September 19, 1941, the United States attorney for the Eastern District of Virginia filed an information against Owens & Minor Drug Co., Inc., of Richmond, Va., alleging shipment within the period from on or about February 14 to on or about July 31, 1940, from the State of Virginia into the State of North Carolina of quantities of aromatic spirit of ammonia, sweet spirit of niter, and camphorated oil which were adulterated, and of a quantity of Dewee's Carminative which was misbranded.

Adulteration of the aromatic spirit of ammonia, sweet spirit of niter, and camphorated oil was alleged in that they purported to be or were represented as drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, but their strength differed from, or their quality or purity fell below, the standards set forth in such compendium in the following respects: The pharmacopoeia prescribes that aromatic spirit of ammonia shall contain in each 100 cubic centimeters not less than 1.7 grams and not more than 2.1 grams of total ammonia (NH_3), and ammonium carbonate corresponding to not less than 3.5 grams as $(NH_4)_2CO_3$, whereas the said aromatic spirit of ammonia contained total ammonia in some instances in excess of the maximum so prescribed, namely, not less than 2,297 grams of total ammonia per 100 cubic centimeters, and contained total ammonia in some instances less than the minimum prescribed, namely, not more than 0.6 gram of total ammonia per 100 cubic centimeters, and it contained less ammonium carbonate than prescribed, namely, ammonium carbonate varying from 3.348 grams to 0.793 gram per 100 cubic centimeters; the United States Pharmacopoeia prescribes that sweet spirit of niter shall contain not less than 3.5 percent of C_2H_5ONO, namely, ethyl nitrite, whereas the said sweet spirit of niter contained less ethyl nitrite than the minimum prescribed, namely, not more than 3.0 percent; and the United States Pharmacopoeia prescribes that camphorated oil shall contain not less than 19 percent of camphor, whereas the said camphorated oil contained less camphor than the minimum prescribed, namely, not more than 17.89 percent; and the respects in which the strength, quality, or

[2] See also Nos. 550, 551.

purity of said drugs differed from the standards set forth in the said compendium were not plainly stated on the labels.

Dewee's Carminative was alleged to be misbranded in that it was for use by man and contained the narcotic or hypnotic substance opium and its label did not bear the name and quantity or proportion of such substance and in juxtaposition therewith the statement "Warning—May be habit forming." It was alleged to be misbranded further in that it was not designated solely by a name recognized in an official compendium, and was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient, including the quantity, kind, and proportion of alcohol.

On October 9, 1941, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of $50.

565. Adulteration of Shores Special Formula Tablets C. T., Special Formula Tablets C. C. T., and Special Formula Tablets S. C. Pink. U. S. v. The Shores Co., Inc. Plea of guilty. Fine, $75. (F. D. C. No. 2908. Sample Nos. 8079-E, 8122-E, 10712-E.)

On June 19, 1941, the United States attorney for the Northern District of Iowa filed an information against the Shores Co., Inc., Cedar Rapids, Iowa, alleging shipment within the period from on or about December 12, 1939, to on or about April 14, 1940, from the State of Iowa into the States of Minnesota and New York, of quantities of the above-named products that were adulterated and misbranded.

The Special Formula Tablets C. T. were alleged to be adulterated in that their strength differed from or their quality fell below that which they purported or were represented to possess, since each of the tablets was represented to contain 10 grains of calcined magnesia and 10 grains of bismuth subnitrate; whereas each of the tablets contained not more than 8.86 grains of calcined magnesia and not more than 8.48 grains of bismuth subnitrate.

The Special Formula Tablets C. C. T. were alleged to be adulterated in that their strength differed from or their quality fell below that which they purported or were represented to possess, since each of the tablets represented to contain kamala and extract of kamala equivalent to 9 grains of kamala and to contain ¼ grain of nicotine; whereas each of the tablets contained kamala and extract of kamala equivalent to not more than 5.81 grains of kamala and only 0.21 grain of nicotine.

The Special Formula Tablets S. C. Pink were alleged to be adulterated in that their strength differed from or their quality fell below that which they purported or were represented to possess, since each of the tablets was represented to contain 1 grain of calcium iodized; whereas each of the tablets contained not less than 1.93 grains of calcium iodized.

On June 19, 1941, the defendant entered a plea of guilty to counts 1, 3, and 5 of the information, and the court imposed a fine of $75 and costs.

566. Adulteration and misbranding of A. B. D. G. Capsules. U. S. v. 15,000 A. B. D. G. Capsules. Default decree of condemnation and destruction. (F. D. C. No. 6068. Sample No. 53409-E.)

These capsules, which were shipped in bulk package, were labeled "A. B. D. G. Capsules Improved," but subsequently a portion were repackaged and labeled "Hain Abedege Improved Vitamins." Each capsule was represented to contain 200 U. S. P. units of vitamin B_1, but examination showed that each one contained not more than 133 International Units (U. S. P. units) of vitamin B_1.

On October 24, 1941, the United States attorney for the Southern District of California filed a libel against 15,000 A. B. D. G. Capsules at Los Angeles, Calif., alleging that the articles had been shipped on or about July 11, 1941, by the International Vitamin Corporation from Brooklyn, N. Y.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, namely, 200 U. S. P. units of vitamin B_1. It was alleged to be misbranded in that the statement on the shipping carton, "200 vitamin B_1 units U. S. P.," was false as applied to an article that contained not more than 133 International Units of vitamin B_1 per capsule.

It was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 3221.

On November 19, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

567. Adulteration and misbranding of Adiron. U. S. v. 20 Bottles, 16 Bottles, and 600 Sample Packages of Adiron. Default decree of condemnation and destruction. (F. D. C. No. 4252. Sample Nos. 60557–E, 60558–E.)

On April 9, 1941, the United States attorney for the Eastern District of Washington filed a libel against 20 bottles each containing 60 tablets, 16 bottles each containing 250 tablets, and 600 sample packages of Adiron at Spokane, Wash., alleging that the article had been shipped in interstate commerce on or about February 5 and March 7, 1941, from Chicago, Ill., by the Lawrence Laboratories; and charging that it was adulterated and misbranded.

Analysis of a sample of the article showed that it contained on iron compound equivalent to approximately 0.7 grain of metallic iron per tablet. Spectrophotometric examination of a sample showed that it contained 67 U. S. P. units of vitamin A per tablet.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, namely, 1,200 U. S. P. XI units of vitamin A per tablet.

It was alleged to be misbranded (1) in that the statement appearing on the label, "Adiron * * * Tablets, each contain * * * 1200 U. S. P. XI Units Vitamin 'A,'" was false; (2) in that the following statements appearing in the labeling, "Adiron is guaranteed to carry these minimum potencies per average tablets: 1,200 USP XI Units Vitamin 'A,'" and "This core is the concentrate of the vitamins, equivalent in vitamins 'A' and 'D' to one-half teaspoonful of fresh U. S. P. Standard cod liver oil," were false when applied to an article which contained only 67 U. S. P. units of vitamin A per tablet; and (3) in that statements, designs, and devices in the labeling which represented that it would be efficacious in the treatment of nutritional (secondary) anemia, that it would make new blood and improve and maintain the health, were false and misleading since it could not be relied upon to produce the effects claimed.

It was also alleged to be adulterated and misbranded in violation of the provisions of the law applicable to foods, as reported in F. N. J. No. 2986.

On May 26, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

568. Adulteration and misbranding of DPS Formula No. 54. U. S. v. 35 Bottles of DPS Formula No. 54. Default decree of condemnation and destruction. (F. D. C. No. 6925. Sample No. 61376–E.)

Examination of this product showed that it was approximately 50 percent deficient in vitamins A, C, and D.

On October 21, 1941, the United States attorney for the District of Oregon filed a libel against 35 bottles, each containing 80 DPS Formula No. 54 tablets, alleging that the article had been shipped on or about July 7 and August 20, 1941, by Dartell Laboratories from Los Angeles, Calif.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, namely, "1,000 International Units of vitamin A, 700 U. S. P. XI units of vitamin D, and 100 International Units of vitamin C."

It was alleged to be misbranded: (1) In that statements appearing on the label, "Each Tablet Contains * * * Vitamin D . . . 700 USP XI Units, Vitamin C . . . 100 International Units, Vitamin A . . . 1000 International Units," were false and misleading since it contained less than the stated amounts of vitamins A, C, and D. (2) In that the following words and device appearing on the label, "DPS Formula No. 54," were false and misleading since they referred and related to the statement "DPS Formula No. 54 . . . Indications: Hyperacidity, Nervousness, Low blood calcium, Moist type skin disorders, Pregnancy and lactation, Soft teeth and bone, Respiratory disorders, Asthma, Sinusitis, Tuberculosis," appearing in a certain catalog entitled "Dartell Formulae" distributed by the consignor and in the possession of the consignee, whereby said words and device suggested and represented that the article was an adequate and effective remedy for the conditions enumerated in the catalog; whereas it was not an adequate and effective remedy for such conditions.

It was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2988.

On December 16, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

569. Adulteration and misbranding of McCollum's Vitamin A and D Tablets. U. S. v. 8 Bottles of McCollum's Vitamin A and D Tablets. Default decree of condemnation and destruction. (F. D. C. No. 5694. Sample No. 61358–E.)

Examination of this product showed that it was more than 50 percent deficient in vitamin A and more than 40 percent deficient in vitamin D.

On September 16, 1941, the United States attorney for the District of Oregon filed a libel against 8 bottles, each containing 60 tablets, of the above-named product at Portland, Oreg., alleging that the article had been shipped on or about July 12 and 25, 1941, by McCollum Laboratories from Hollywood, Calif.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, namely: "Each tablet contains 3000 International Units of Vitamin A * * * and 300 International Units of Vitamin D," since each tablet contained much less than 3,000 International Units of vitamin A and 300 International Units of vitamin D. It was alleged to be misbranded in that the above-quoted statement was false and misleading.

It was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2989.

On December 21, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

570. Adulteration and misbranding of Bio Vita Vitamin Oil. U. S. v. 23 Gallon Cans of Bio Vita Vitamin Oil. Default decree of condemnation and destruction. (F. D. C. No. 4378. Sample No. 60505–E.)

This veterinary product, in addition to containing a smaller amount of vitamin D than that represented in the labeling, also contained false and misleading therapeutic claims.

On April 21, 1941, the United States attorney for the District of Massachusetts filed a libel against the above-named product at Lexington, Mass., alleging that it had been shipped by Bioproducts, Inc., from Astoria, Oreg., on or about February 11, 1941; and charging that it was adulterated and misbranded.

Biological examination of a sample of the article showed that it contained not more than 175 U. S. P. units of vitamin D per gram.

The article was alleged to be adulterated in that its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

It was alleged to be misbranded in that the following statements on the label were false and misleading since it would not be efficacious for such purposes: "250 USPXI Units Vitamin D per gram * * * Vitamin A is important to good fur, to build resistance to respiratory diseases, to insure good breeding, to promote growth, to prevent urinary calculi. Aids in maintaining good skin condition."

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2987.

On July 8, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

571. Adulteration and misbranding of Codroil. U. S. v. 20 Drums of Codroil. Default decree of condemnation ordering that the product be relabeled and sold as ordinary feed. (F. D. C. No. 4400. Sample No. 29068–E.)

This product was represented to contain 3.71 percent of cod-liver-oil extract containing 4,833 units of vitamin A per gram, which would indicate that the product contained 179 units of vitamin A per gram; whereas examination showed that it contained only 88 units of vitamin A per gram. Furthermore, no statement of contents appeared on the container.

On April 19, 1941, the United States attorney for the Northern District of Ohio filed a libel against 20 drums, each containing 100 pounds, of Codroil at Ashland, Ohio, alleging that the article had been shipped in interstate commerce by Pho-So-Ash Products Corporation from Kendallville, Ind., on or about February 10, 1941; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, namely, "Ingredients—Cod liver oil extract 3.71 per cent (4833 units vitamin A per gram * * *)."

It was alleged to be misbranded (1) in that the above-quoted statement on the label was false since it was incorrect; and (2) in that the package (drum) did not bear an accurate statement of the quantity of contents.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2857.

On July 3, 1941, no claimant having appeared, judgment of condemnation was entered and it was ordered that the product be relabeled and sold as ordinary feed.

572. Adulteration of Gynantrin. U. S. v. 1525-cc. Vials of Gynantrin. Default decree of condemnation and destruction. (F. D. C. No. 5600. Sample No. 62510–E.)

This product was represented on the label to possess a potency of 100 rat units of anterior pituitary hormone per cc.; whereas examination showed that it possessed a potency of not more than 12 rat units per cc.

On September 8, 1941, the United States attorney for the Northern District of Illinois filed a libel against the above-named product at Chicago, Ill., alleging that it had been shipped on or about February 7, 1941, by Difco Laboratories from Detroit, Mich.; and charging that it was adulterated. When shipped it was labeled in part: "Difco Anterior Pituitary Sex Hormone Solution 100 Rat Units per CC." Subsequently it was relabeled in part: "Gynantrin * * * Anterior Pituitary Gonad."

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely, 100 rat units per cc.

On October 15, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

573. Adulteration and misbranding of isopropyl alcohol compound. U. S. v. 214½ Dozen 6-Fluid-Ounce Packages and 39½ Dozen 16-Fluid-Ounce Packages of Paramount Brand Isopropyl Alcohol Compound. Default decree of condemnation and destruction. (F. D. C. No. 4628. Sample No. 57311–E.)

Examination of samples of this product showed that it contained only 10 percent by volume of isopropyl alcohol, whereas it was labeled "Isopropyl Alcohol 25 Percent." Furthermore, isopropyl alcohol rubbing compounds usually contain a much higher proportion of isopropyl alcohol than the amount found and even much higher than the amount declared.

On May 7, 1941, the United States attorney for the Eastern District of Arkansas filed a libel against the above-named product at Jonesboro, Ark., alleging that it had been shipped by Rozelle, Inc., from St. Louis, Mo., on or about October 8, 1940; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess, namely, "Isopropyl Alcohol 25 Percent." It was alleged to be misbranded in that the statement "Isopropyl Alcohol Compound" was misleading for the reason that isopropyl alcohol rubbing compounds sold on the market contain a much higher proportion of isopropyl alcohol.

On June 18, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS[3]

574. Misbranding of New Food. U. S. v. Parke D. Brollier (Parke-Lee Food Co.). Plea of nolo contendere. Judgment of guilty. Fine, $100 and costs. (F. D. C. No. 2912. Sample No. 15001–E.)

The labeling of this product bore false and misleading representations regarding its constituents and its efficacy in the conditions indicated hereinafter.

On April 21, 1941, the United States attorney for the Northern District of Ohio filed an information against Parke D. Brollier, trading as Parke-Lee Food Co., Lorain, Ohio, alleging shipment on or about February 8, 1940, from the State of Ohio into the State of Iowa of a quantity of New Food which was misbranded.

Analysis showed that the product consisted of ground and roasted flaxseed.

It was alleged to be misbranded in that the statements, "New Food * * * The Original Natural * * * Food, * * * Newfood is, as the trade name implies, an entirely new type of food. * * * The nutritional value of this all-vegetable auxiliary food with its natural * * * minerals, fats, proteins, gives * * * extra nourishment and strength. This food contains an all-vegetable mucin (mucilage) * * * Newfood is an excellent auxiliary food," appearing in the labeling, were false and misleading in that they represented that the article was a new food; that it possessed such nutritional value that it would supply important amounts of minerals, fats and proteins and thus give extra

[3] See also Nos. 541, 542, 544–553, 555–559, 567, 568, 570.

nourishment and strength, and would furnish an appreciable amount of mucin (mucilage); whereas it would not be of value for such purposes.

It was alleged to be misbranded further in that the statements "Modern articles of food in our everyday diet may be responsible for many distressing symptoms. Methods of preparation may have destroyed much of the vital constituents, and synthetic compounds that are minus essential elements being substituted for natural products, may also be responsible for dietary deficiencies. We live principally on sugar and starches, neither of which are greatly destroyed by the process of cooking," and "This food will be a pleasant and effective addition to the diet of any person of any age," appearing in the circular, were false and misleading since they represented that it would supply vital constituents which are lacking in modern foods or might have been destroyed by modern methods of preparation, and which would be an effective addition to the diet; whereas it would not be of value for such purposes.

It was alleged to be misbranded further in that the statements "(Vitamin 'F') * * * food consisting essentially of a natural blend of the seed coat and embryo of the seeds of linum usitatissimum (Flax) U. S. P.," borne on the label, and "Food * * * with * * * (Vitamin 'F'), * * * Eminent food authorities are agreed that there exists a certain fatty acid deficiency, principally a deficiency of Linolic, Insolinolic and Linolinic or Unsaturated Fatty Acids (Vitamin 'F'), * * * Scientifically processed and prepared from a natural blend of the seed coat and embryo of a selected variety of seeds of linum usitatissimum (flax) U. S. P. * * * The Linolic, Insolinic and Linolinic, Unsaturated Fatty Acids (Vitamin 'F')," appearing in the circular, were misleading in that the statement "a natural blend of the seed coat and embryo of a selected variety of seeds of linum usitatissimum (flax)," was a misleading description of ground and roasted flaxseed, and authorities are not agreed that the term "Vitamin F" is a proper name to be applied to the unsaturated fatty acids, nor are they agreed that there are fatty acid deficiencies in the ordinary human diet.

It was alleged to be misbranded further in that certain statements in the labeling were false and misleading in that they represented that the article would be efficacious in the treatment of symptoms of diabetes, stomach and intestinal ulcers, high blood pressure and indigestion; that it would be beneficial to the diabetic and would aid diabetics to reduce their sugar and would assist in keeping diabetics sugar free, and that it would give diabetics extra nourishment and strength; that it would be efficacious in the treatment of those who are suffering with stomach and intestinal ulcers; that it would be efficacious in the treatment of high blood pressure; that it would neutralize excess acid and give relief for acid indigestion; and that it would be efficacious to correct dietary deficiencies, whereas it would not be efficacious for such purposes.

It was alleged to be misbranded further in that its label did not bear the common or usual name of the food, namely, flaxseed or linseed, prominently placed thereon with such conspicuousness, as compared with other words, statements, designs or devices in the labeling, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2820.

On May 23, 1941, the defendant having entered a plea of nolo contendere, he was adjudged guilty and fined $100.

575. Misbranding of Robinson Spring Water. U. S. v. Ralph V. Bloomhuff and Charles F. Bloomhuff. Pleas of guilty; fines of $150 each. (F. D. C. No. 929. Sample Nos. 54577–D, 66050–D.)

On May 13, 1940, the United States attorney for the Southern District of Mississippi filed an information against Ralph V. Bloomhuff and Charles F. Bloomhuff, Jackson, Miss., alleging shipment in interstate commerce on or about August 2 and July 26, 1939, from the State of Mississippi into the States of Michigan and Florida of quantities of Robinson Spring Water which was misbranded. It was labeled in part: "A Natural Diuretic Eliminant Water."

Analysis showed that the article was a slightly mineralized water similar in composition to Ohio River water.

The article was alleged to be misbranded in that the statement "used in treating diabetes, kidney and bladder trouble," borne on the label, was false and misleading since it would not be efficacious for such purposes.

On November 5, 1941, pleas of guilty were entered and the court imposed fines of $150 upon each defendant.

576. Misbranding of Hilltop Wor-Mor Powder, Hilltop Poultry Breathing Stimulator, and Hilltop Kure-Mor Intestinal Astringent. U. S. v. Hilltop Farm Feed Co., Frank E. Moore, and Fred H. Moore. Pleas of guilty. Fines, $150. (F. D. C. No. 2978. Sample Nos. 8382–E to 8384–E, incl.)

On June 9, 1941, the United States attorney for the District of Minnesota filed an information against Hilltop Farm Feed Co., Minneapolis, Minn., Frank E. Moore, and Fred H. Moore, alleging delivery for introduction in interstate commerce within the period from on or about March 29 to on or about April 25, 1940, from the State of Minnesota into the State of Wisconsin of quantities of poultry remedies that were misbranded. They were labeled in part: "Hilltop * * * Worm Powder Wor-Mor Powder"; "Hilltop Poultry Breathing Stimulator"; or "Hilltop * * * Intestinal Astringent Kure-Mor."

Analysis of a sample of the Wor-Mor Powder showed that it consisted essentially of copper sulfate, iron sulfate, plant material including nux vomica and anise, and nicotine sulfate. It was alleged to be misbranded in that the statements appearing on the cartons representing that it was efficacious in the control of worms in poultry and that it was efficacious to eliminate and eradicate worms in poultry, were false and misleading since it was not efficacious for such purposes. It was alleged to be misbranded further in that the statements on the carton, "Directions Mix 8 ounces of Hilltop Wor-Mor Powder into 100 lbs. of mash. Feed for two days and then repeat for one day two weeks later. For control of worms repeat this plan every month after the chicks are one month old throughout their entire life. It pays. The cost is small. Don't feed wormy chickens. Eliminate the Worms. Hilltop Kure-Mor should be fed in all drinking water for its healing * * * effects during the above treatment and for a few days following," regarding another drug product sold by said defendant, i. e., Kure-Mor, were false and misleading in that they represented that Kure-Mor if fed in drinking water during treatment for worms would have a healing effect; whereas it would not.

Analysis of a sample of the Hilltop Poultry Breathing Stimulator showed that it consisted essentially of phenolic compounds such as cresol and guaiacol, and volatile oils such as eucalyptus, anise, and camphor, incorporated in a saponified base. Bacteriological examination showed that it was not antiseptic. It was alleged to be misbranded in that statements appearing on the bottle label representing that it was a poultry breathing stimulator; that it would be efficacious as a respiratory stimulant that would tend to alleviate bronchial conditions; that it was efficacious as an antiseptic, as a gastro-intestinal antiseptic, and as an intestinal anti-ferment; that it would be efficacious to affect favorably the respiratory tract, hinder and act against the spread of contagions such as roup, catarrh, influenza, brooder pneumonia, chickenpox, diphtheria, and other diseases of the respiratory tract in poultry flocks; and that it would penetrate the nostrils, were false and misleading since it would not be efficacious for such purposes.

Analysis of a sample of the Hilltop Kure-Mor showed that it consisted essentially of compounds of magnesium and potassium sulfate, nitrate, chlorate, and dichromate. It was alleged to be misbranded in that statements appearing on the bottle label representing that it was efficacious as an intestinal astringent; that it had great merit for poultry of all ages and would maintain poultry in good condition; that it was efficacious in the treatment of poultry which was out of condition and in need of a regulator and conditioner; that it would be efficacious as an aid in better starting of young poultry, would help the chick digest the egg yolk the first few days, and act as a bowel regulator and conditioner at all times; that it would be efficacious to soften and remove the caked waste, without causing bleeding, in chicks that had become "pasted up" with bowel trouble; that it would be efficacious to flush the system of chicks of poisonous deposits in the intestines; and that it would increase the consumption of water and cause heavier egg production, were false and misleading since it would not be efficacious for such purposes.

On June 9, 1941, pleas of guilty having been entered by the defendants, the court imposed a fine of $50 against each.

577. Misbranding of Crawford's Ridia. U. S. v. 20 Bottles of Crawford's Ridia. Default decree of condemnation and destruction. (F. D. C. No. 3826. Sample No. 55743–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the treatment of diabetes.

On February 20, 1941, the United States attorney for the District of Oregon filed a libel against 20 bottles of Crawford's Ridia at Portland, Oreg., alleging that the article had been shipped on or about January 10, 1941, by Crawford Foods, Inc., from San Jose, Calif.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of alfalfa with smaller proportions of mint.

It was alleged to be misbranded in that representations in an accompanying circular entitled "Health Chronicle" that it was a substitute for the secretions of the pancreas and would be efficacious for the relief of suffering diabetics; that each tablet contained a potency equal to 2 insulin units; that by its use insulin sickness would vanish; that insulin stiffness or muscular pains that grow on the patient after a prolonged use of insulin would slowly leave the body; that the blurred vision and partial blindness induced by insulin would gradually be cleared; and that it was a natural remedy and health food adjuvant, were false and misleading since it would not be efficacious for such purposes.

It was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2823.

On April 17, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

578. Misbranding of Enrich and Ritamine. U. S. v. 40 Bottles of Enrich and Ritamine. Default decee of condemnation and destruction. (F. D. C. Nos. 4884, 4885. Sample Nos. 40816–E, 40821–E.)

On June 6, 1941, the United States attorney for the Eastern District of Pennsylvania filed a libel against 14 16-fluid-ounce bottles and 6 8-fluid-ounce bottles of Enrich, and 8 75-day, 4 35-day, and 8 10-day packages of Ritamine at Philadelphia, Pa., alleging that the articles had been shipped within the period from on or about March 28 to on or about May 13, 1941, by American Dietaids Co., Inc., from Yonkers, N. Y.; and charging that they were misbranded.

Analysis of a sample of Enrich showed that it contained per fluid ounce—peptonized iron (650 milligrams), soluble manganese citrate (54 milligrams), calcium glycerophosphate (170 milligrams), and vitamin B_1 (200 U. S. P. units); analyses of samples of Ritamine, which consisted of black and brown capsules, showed that the black capsules contained vitamin A (12,800 units), vitamin B_1 (200 units), vitamin C (226 units), and vitamin D (600 units); and that the brown capsules contained compounds of calcium, iron, phosphorus, copper, and iodine with small proportions of compounds of other elements, and an oil such as wheat-germ oil.

Enrich was alleged to be misbranded: (1) In that statements on an accompanying placard in the window display of the consignee which suggested or implied that women normally require excessive amounts of iron to prevent the development of anemia; and which represented that its use would benefit nerves, glands, and other organs; would promote energy, endurance, appetite, vigor, vitality, sunny disposition, and radiant complexion; and that the product was an adequate treatment for anemia due to lack of iron, were false and misleading since women do not normally require excessive amounts of iron to prevent the development of anemia, and the use of the article would not fulfill such promises of benefits stated and implied. (2) In that the designation "Enrich" on the carton and bottle labels constituted a false and misleading device since it suggested and represented to purchasers that use of the article would enrich the blood, such meaning having been acquired as the result of the following statements on placards in the consignee's window display and in circulars on a counter in the consignee's store, "Are You Anemic due to lack of iron in your blood? New Enrich tonic brings genuine food-iron to the blood * * * Enriched Blood * * * It is vital that the blood be rich in iron. Take—Enrich"; whereas its use could not be depended upon to enrich the blood. (3) In that the following statements appearing on the carton and the bottle labels, "A Dietary Supplement * * * contains * * * Calcium * * * as the glycerophosphates," were false and misleading in the absence of a disclosure of the material fact that the amount of calcium glycerophosphate would furnish but a small fraction of the normal calcium requirement when the article was taken in accordance with the directions for use appearing on the bottle label, namely, "2 teaspoonfuls 4 times daily * * * For children, 1 teaspoon 4 times daily."

Ritamine was alleged to be misbranded in that representations in its labeling that its use would supply vitamins and minerals needed for various tissues, organs, and functions, were false and misleading since it would not fulfill the promises of benefits stated and implied.

On June 28, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

579. Misbranding of Lishus and Bekus Puddy. U. S. v. 19 Cases of Lishus and 18 Cases of Bekus Puddy. Default decree of condemnation and destruction. (F. D. C. No. 4043. Sample Nos. 55692–E, 55693–E.)

On April 7, 1941, the United States attorney for the District of Oregon filed a libel against the above-named products at Portland, Oreg., alleging that the articles had been shipped in interstate commerce on or about January 13, 1941, by Dr. Jackson Foods from Brooklyn, N. Y.; and charging that they were misbranded.

Analyses of samples of the articles showed that they consisted essentially of flaxseed, rice, rice polishings, wheat, and wheat bran.

Both articles were alleged to be misbranded (1) in that the statement on the carton, "If troubled with Acid Stomach or fermentation, etc., do not use sugar,—Cook raisins or dates in with the cereal if sweet is required," was false and misleading since with or without raisins or dates they did not constitute an adequate treatment for acid stomach, fermentation, etc.; (2) in that the pictures of a robust man accompanied by the legends "Dr. Jackson at 80," and "Photo of Robert G. Jackson, M. D., at 60," were false and misleading since use of the articles could not be depended upon to produce or maintain robustness; and (3) in that statements appearing in a leaflet entitled "Service Bulletin #13," which represented that they were especially designed to relieve constipation and get rid of its cause by natural means; that it would furnish sufficient roughage to stimulate muscular activity of the bowels and that it would furnish enough minerals to stimulate and support nervous control of those muscles and keep them on the job until the waste had been discharged; and cause three to five evacuations a day in a person ordinarily having but two movements a week, were false and misleading since the articles would not be efficacious for such purposes.

Lishus was also alleged to be misbranded further under the provisions of the law applicable to foods, as reported in F. N. J. No. 2995.

On May 13, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

580. Misbranding of Quaker Puffed Wheat Sparkies. U. S. v. 154 Cases of Quaker Puffed Wheat Sparkies. Default decree of condemnation. Product ordered delivered to a Federal institution. (F. D. C. No. 4966. Sample No. 47829–E.)

This product was falsely labeled regarding its vitamin content and its therapeutic qualities.

On June 23, 1941, the United States attorney for the Eastern District of Michigan filed a libel against 154 cases, each containing 24 4-ounce packages, of Quaker Puffed Wheat Sparkies at Detroit, Mich., alleging that the article had been shipped by the Quaker Oats Co. from Cedar Rapids, Iowa, on or about March 18, 1941; and charging that it was misbranded. It was labeled in part: (Box label) "The 'Vitamin Rain' Breakfast Food."

The article was alleged to be misbranded in that designs, devices, and statements in the labeling were false and misleading since they created the impression that it contained vitamins A, B_1, C, D, and G in consequential amounts, and that it would be effective in preventing colds and infections, in producing healthy nerves, normal growth, good teeth, strong bones, and other desirable attributes; whereas it contained no vitamins A or C and only inconsequential amounts of vitamins B_1 and G, and it would not be effective in preventing colds and infections, nor in producing healthy nerves, normal growth, good teeth, strong bones, and other desirable attributes.

It was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

On December 3, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to a nearby Federal institution.

581. Misbranding of thiamin chloride B_1. U. S. v. 239 Bottles of Thiamin Chloride B_1 with Accompanying Labeling. Default decree of condemnation. Product ordered distributed to local hospitals. (F. D. C. No. 4826. Sample No. 50234–E.)

On May 24, 1941, the United States attorney for the District of Maryland filed a libel against 239 bottles, each containing 100 tablets, of thiamin chloride B_1 at Baltimore, Md. (on June 4, 1941, the libel was amended to include accompanying labeling), alleging that the article had been shipped by Geo. M. Beringer, Inc., from Camden, N. J., on or about November 11, 1940; and charging that it was misbranded in that representations in the labeling regarding its efficacy in the correction of the alcoholic habit, nervous indigestion, nervous headaches, and neuralgic pain, were false and misleading since it would not be efficacious for such purposes.

Microscopic examination of a sample of the article showed that it was essentially a milk sugar tablet containing crystalline thiamin chloride (vitamin B_1).

It also was alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2990.

On July 12, 1941, no claimant having appeared, judgment of condemnation was entered and the product was delivered to a local hospital for clinical use.

582. Misbranding of Filto-Vapor Nasal Filter Outfit. U. S. v. 56 Dozen Packages of Filto-Vapor Nasal Filter Outfits. Default decree of condemnation and destruction. (F. D. C. No. 4733. Sample No. 19200–E.)

On May 13, 1941, the United States attorney for the Western District of Pennsylvania filed a libel against the above-named product at Pittsburgh, Pa., alleging that it had been shipped on or about January 16, 1941, by Medical Products Institute, Inc., from Cincinnati, Ohio; and charging that it was misbranded.

Examination of samples of the article showed that it consisted of a pair of nasal filters, one detachable band, tweezers, filter pads, a bottle labeled "Filto-Vapor Cold Tablets," and a bottle labeled "Filto-Vapor Nasal Filter Pad Fluid." Analyses showed that the cold tablets consisted essentially of acetophenetidin, aspirin, and caffeine; and that the nasal filter pad fluid consisted essentially of camphor, menthol, eucalyptol, pine-needle oil, alcohol, and a vegetable oil.

The article was alleged to be misbranded: (1) In that the following statements, (display carton) "A new scientific continuous treatment for Colds Sinus, Sore Throat, Coughs"; (retail carton) "Aids in relief of Colds. Sinus. Sore Throat, Bronchitis and Grippe"; (cold tablets, carton) "Cold Tablets Filto-Vapor Cold Tablets Aid In Relief Of Common Colds and Grippe"; and (filter pad fluid, label) "Filto-Vapor Nasal Filter Pad Fluid Aids in Relief Of Common Colds, Sinus, Sore Throat And Bronchitis," were false and misleading since it would not be efficacious for such purposes. (2) In that the label for the nasal filter pad fluid listed "Olei Recinolei" (castor oil) was an active ingredient, whereas that ingredient was not an active ingredient, but constituted a portion of the vehicle for the active ingredients. (3) In that the retail container of the cold tablets did not bear a statement of the active ingredients. (4) In that aspirin had not been declared by its common or usual name on the label for the cold tablets but had been declared as acetylsalicylic acid. (5) In that the statements of active ingredients appearing on the labels for the cold tablets and nasal filter pad fluid were in such small type as to be practically illegible.

On September 18, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

583. Misbranding of Pinolator inhaler and medicament. U. S. v. 83 Packages of Pinolator and "Breath O' The Forest" Aromatic. Default decree of destruction. (F. D. C. No. 4006. Sample No. 43169–E.)

On March 21, 1941, the United States attorney for the Western District of Missouri filed a libel against the above-named product at Kansas City, Mo., alleging that it had been shipped on or about January 2, 1941, by the Pinolator Co. from Minneapolis, Minn.; and charging that it was misbranded.

Analysis of a sample of the "Breath O' The Forest" Aromatic showed that it consisted essentially of menthol, camphor, pine oil, thymol, and a benzoate dissolved in a mixture of alcohol (60 percent, or 288 minims per fluid ounce), and water.

The article was alleged to be misbranded: (1) In that statements in the labeling representing that it would provide soothing relief and comfort in symptoms of common colds, sinus, bronchitis, asthma, and hay fever, with such typical claims as "The blessings that will result from the first inhalation will be like a direct answer to prayer," "In daily thorough use of the Pinolator your sinus distress may become only a bad memory," "Pinolator will stop short the all too familiar symptoms of a fresh cold," and "The Pinolator user may pass through the worst hay fever season without serious discomfort," were false and misleading since it would not be efficacious for the purposes recommended. (2) In that the statement on the bottle label and carton, "Ethyl alcohol 69% 330 minims per ounce," was false and misleading since the drug contained materially less than the stated amount of alcohol. (3) In that the carton failed to bear a statement of the name of each of the active ingredients, including the quantity, kind, and proportion of alcohol. (4) In that the carton did not bear a statement of the quantity of its contents.

On July 28, 1941, no claimant having appeared, judgment was entered ordering that the product be destroyed.

584. Misbranding of Orrine No. 1. U. S. v. 138 Packages of Orrine No. 1. Default decree of condemnation and destruction. (F. D. C. No. 3428. Sample No. 12879–E.)

The labeling of this product falsely represented that its use would be helpful in relieving or lessening the desire for alcohol.

On November 25, 1940, the United States attorney for the Northern District of California filed a libel against 138 packages of Orrine No. 1 at San Francisco, Calif. On December 20, 1940, the libel was amended to cover an additional shipment of 75 packages. The libel as amended alleged that the article had been shipped by the Orrine Co. from Washington, D. C., on or about April 9 and August 20, 1940; and charged that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of gold chloride, hyoscine hydrobromide, ammonium, chloride, and cinchona alkaloids.

The article was alleged to be misbranded in that representations in the labeling that it would be efficacious in lessening or relieving the desire or craving for liquor, were false and misleading.

On June 21, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

585. Misbranding of hair tonic. U. S. v. 57 Dozen 8-Fluid-Ounce Bottles and 15 Dozen 16-Fluid-Ounce Bottles of West Point Hair Tonic. Default decree of condemnation and destruction. (F. D. C. No. 4014. Sample No. 46916–E.)

On March 19, 1941, the United States attorney for the District of New Jersey filed a libel against the above-named product at Newark, N. J., alleging that it had been shipped in interstate commerce on or about January 22, 1941, by Associated Brands, Inc., from Brooklyn, N. Y.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of alcohol, water, castor oil, benzyl benzoate, and benzoin.

The article was alleged to be misbranded in that the following statements were false and misleading, (carton) "Natural Vegetable Oil Hair Tonic * * * West Point Hair Tonic wakes up tight, lazy scalps, * * * and brings new life * * * to hair. * * * For Thinning Hair * * * Teach the children to use West Point Hair Tonic. It will insure their having healthy, beautiful hair when they grow older," and (label) "Natural Vegetable Oil Hair Tonic," since they represented that it would be efficacious for the purposes recommended; whereas it would not be efficacious for such purposes.

On July 18, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

586. Misbranding of Newbro's Herpicide. U. S. v. 96 Bottles of Newbro's Herpicide and 48 Bottles of Newbro's Herpicide, Odorless. Default decree of condemnation and destruction. (F. D. C. No. 3889. Sample No. 34230–E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the treatment of dandruff, falling hair, and hair disorders, and failed to bear the names of the active ingredients.

On February 27, 1941, the United States attorney for the District of New Jersey filed a libel against 96 bottles of Newbro's Herpicide and 48 bottles of Newbro's Herpicide, Odorless, at Jersey City, N. J., alleging that the article had been shipped in interstate commerce on or about October 14, 1940, by the Herpicide Co. from New York, N. Y.; and charging that it was misbranded.

Analyses showed that both types of the article consisted essentially of salicylic acid, glycerin, water, alcohol, and small amounts of brucine and aromatics.

It was alleged to be misbranded in that the following statements and designs appearing on the label were false and misleading since it would not be efficacious for the purposes for which it was recommended. "Recommended for * * * excess loss of hair * * * [3 line drawings of heads with little or no hair labeled "Going! Herpicide may save it," "Going!! Herpicide may save it," and "Gone!!! Too late for Herpicide"] * * * Destroy the cause you remove the effect * * * Especially compounded for the Scientific Treatment of Obstinate Dandruff—Falling Hair Scalp and Hair Disorders." It was alleged to be misbranded further in that the label did not bear the common or usual names of the active ingredients.

On July 18, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

587. Misbranding of Bo-Go-Ha-Ma Mineral Springs Water. U. S. v. 32 Jugs of Mineral Water. Default decree of condemnation and destruction. (F. D. C. No. 6191. Sample No. 49865–E.)

On November 7, 1941, the United States attorney for the Eastern District of Louisiana filed a libel against 32 gallon jugs of mineral water at New Orleans, La., alleging that the article had been shipped in interstate commerce on or about October 20, 1941, by Stafford Mineral Springs Co. from Vosburg, Miss.; and charging that it was misbranded.

Analysis of a sample of the article showed that it was a mildly alkaline water similar to Washington tap water, except that it contained about twice the amount of dissolved mineral matter.

It was alleged to be misbranded in that the statement "It is * * * very soothing and healing to the kidneys and bladder" was false and misleading since it would be neither soothing nor healing to the kidneys.

It was also alleged to be adulterated under the provisions of the law applicable to foods, as reported in F. N. J. No. 2830.

On December 24, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

588. Misbranding of mineral oil. U. S. v. 141 Bottles of Russian Type Mineral Oil. Default decree of condemnation and destruction. (F. D. C. No. 4401. Sample No. 50228–E.)

This product was mineral oil of domestic origin. It was labeled in conspicuous type "Russian Type Mineral Oil," and in much smaller type "Made in U. S. A."

On April 19, 1941, the United States attorney for the Eastern District of Virginia filed a libel against the above-named product at Richmond, Va., alleging that it had been shipped on or about March 24, 1941, by Adde, Inc., from Baltimore, Md.; and charging that it was misbranded in that the conspicuous statement on the label, "Russian Type Mineral Oil," was misleading as applied to a domestic mineral oil.

On October 16, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

589. Misbranding of Lurin. U. S. v. 296 Bottles of Lurin. Default decree of condemnation and destruction. (F. D. C. No. 4808. Sample No. 62133–E.)

On May 22, 1941, the United States attorney for the Northern District of Illinois filed a libel against 296 bottles of Lurin at Chicago, Ill., alleging that the article had been shipped on or about April 8 and 19, 1941, by the Lurin Co. from Cleveland, Ohio; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of aluminum hydroxide (2.1 grams per 100 cc.) and water flavored with peppermint oil.

The article was alleged to be misbranded (1) in that statements on the label, "Alcoholic Over Indulgence" and "Where Used in the Treatment of Active Peptic Ulcers," were false and misleading since it was not an adequate treatment for those conditions; (2) in that the statement on the label, "Combines with at least 12 times its volume of N/10 Hydrochloric Acid," was false and misleading since the volume of aluminum hydroxide that it contained was sufficient to combine with only 8.08 volumes of N/10 hydrochloric acid; and (3) in that the statement on the label, "Contents 8 Fl. Oz.," was false and misleading since it contained less than 8 fluid ounces.

On September 16, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

590. Misbranding of Waft-Surgical. U. S. v. 2¼ Dozen Packages of Waft-Surgical. Default decree of condemnation and destruction. (F. D. C. No. 5430. Sample No. 27876–E.)

On August 26, 1941, the United States attorney for the Southern District of Indiana filed a libel against the above-named product at Evansville, Ind., alleging that it had been shipped on or about May 30, 1941, by the Federal Cosmetic Sales Corporation from Springfield, Ill.; and charging that it was misbranded. It was labeled in part: "Waft-Surgical Antiseptic-Disinfectant-Deodorant-Fungicide-Germicide-Parasiticide."

Analysis of a sample of the article showed that it consisted essentially of water, formaldehyde, small amounts of turpineol, and a yellow-green coloring material.

It was alleged to be misbranded: (1) In that representations in the labeling that it would be efficacious as an antiseptic, disinfectant, fungicide, germicide

or parasiticide in the dilutions suggested; that it would be of value as a wet dressing or irrigation in wounds in these dilutions; that it would penetrate the environment; that it would inhibit disease-producing micro-organisms; that it would be efficacious for the sterilization of surgical instruments and that it would be a reliable fungicide or germicide for animals, were false and misleading since it would not be efficacious for such purposes. (2) In that the label did not contain the common or usual names of the active ingredients.

On October 2, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

591. Misbranding of Hercules Congestors. U. S. v. 5 Hercules Congestors Model Regulator #500 and 6 Hercules Congestors Model Super 900. Default decree of condemnation and destruction. (F. D. C. No. 5082. Sample No. 61021–E.)

On July 7, 1941, the United States attorney for the Western District of Washington filed a libel against the above-named articles at Seattle, Wash., alleging that they had been shipped on or about May 26, 1941, by Holdfast Truss Co. from Oakland, Calif.; and charging that they were misbranded.

Examination of samples showed that the articles consisted of a metal vacuum pump and a large glass tube bearing at one end a soft rubber collar and closed at the other end with a metal cap which was threaded to screw into the pump.

The articles were alleged to be misbranded (1) in that the following statements in a circular enclosed in each package by the dealer were false and misleading, "Organ Developer. This developer removes all obstructions in the organ, propels the blood rapidly through the disordered channels, and a quick and favorable result follows. * * * This simple apparatus is called upon to increase the lost energy and remove the loss of strength. * * * In most cases results come in a short time, while others of long standing require the patient use of the developer for five or six weeks"; and (2) in that the label failed to bear the name and address of the manufacturer, packer, or distributor.

On September 29, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

592. Misbranding of Ayds Candy. U. S. v. 73 Packages of Ayds Easy Reducing Plan Candy (and 5 other seizure actions against Ayds Candy). Default decrees of condemnation. Portion of product ordered destroyed; remainder ordered distributed to charitable institutions. (F. D. C. Nos. 2334, 3600, 3601, 3670, 3999, 4752. Sample Nos. 15617–E, 27514–E, 29201–E, 29202–E, 35926–E, 35935–E.)

The labeling of this product bore false and misleading representations regarding its efficacy as a reducing agent.

Between July 11, 1940, and May 23, 1941, the United States attorneys for the Eastern District of Arkansas, Southern District of Ohio, and the Southern District of Alabama filed libels against 73 packages of Ayds Candy at Little Rock, Ark., 160 various-sized boxes at Cincinnati, Ohio, and 97 various-sized boxes at Mobile, Ala., alleging that the article had been shipped in interstate commerce within the period from on or about May 4 to on or about December 10, 1940, by the Carlay Co., Fuller Laboratories, or Fuller Co., from Chicago, Ill.; and charging that it was misbranded.

The article was alleged to be misbranded in that the name "Ayds," the designs of slender female figures, designs of slender female figures superimposed on obese female figures, a picture entitled "Before," showing obese woman and one entitled "After," showing, presumably, the same individual after having lost 40 pounds, and a poster with picture of a female figure with the words underneath "Now Weighs 130 Lbs. Weighed 160 Lbs.," appearing in the labeling of the various lots, together with statements in circulars accompanying the various shipments, were false and misleading in that the said words, designs, pictures, and statements created the impression in the mind of the reader that the article, when used as directed and in conjunction with and as a part of the so-called plans referred to in the circulars as No. 1 Plan and No. 2 Plan, would because of its composition and characteristics, be of substantial value in reducing body weight; that it would aid the consumer to reduce pleasantly and without effort and would aid the consumer to keep the weight down after having reduced to the desired weight; and that it would aid the consumer to cut down on the amount of food eaten without feeling pangs of hunger, distress, faintness or debilitation; whereas it would not be efficacious for the purposes suggested.

It also was alleged to be misbranded in violation of the provisions of the law applicable to foods, as reported in notices of judgment on foods.

Within the period from September 20, 1940, to August 19, 1941, no claimant having appeared, judgments of condemnation were entered and those lots located at Cincinnati and Mobile were ordered distributed to various charitable institutions, and the remaining lots were ordered destroyed.

593. Misbranding of Ayds Candy. U. S. v. 17 Boxes of Ayds Candy. Default decree of condemnation and destruction. (F. D. C. No. 4269. Sample No. 28268-E.)

On April 9, 1941, the United States attorney for the District of Columbia filed a libel against 17 boxes of Ayds Candy, alleging that the article was in interstate commerce in the District of Columbia at the Vita Health Food Co., in the City of Washington, District of Columbia; and charging that it was misbranded.

The article was alleged to be misbranded (1) in that representations in the labeling regarding its efficacy in effecting reduction of body weight in the consumer were false and misleading since they were incorrect; and (2) in that the combination of letters "Ayds Candy," appearing on the package label, constituted a false and misleading device since it meant to purchasers that the article was an appropriate and effective aid in reducing body weight—having acquired such meaning because of statements and designs appearing in a circular bearing the title legends "Now! Many Lose Weight by New, Easy Plan. Ayds Easy Reducing Plan and Candy": whereas the candy was not an effective and appropriate aid in reducing body weight.

It also was alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2976.

On May 1, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

594. Misbranding of Slend-R-Form Candy. U. S. v. 91¼ Dozen Boxes of Slend-R-Form Candy (and 12 other seizure actions against Slend-R-Form Candy). Default decrees of condemnation. Portions of product ordered distributed to charitable institutions; remainder ordered destroyed. (F. D. C. Nos. 3599, 3916, 3924, 3998, 4017, 4201, 4678, 4768, 5048, 5239, 5240, 5749, 5758. Sample Nos. 5181-E, 11404-E, 22302-E, 38942-E, 39706-E, 43590-E, 44652-E, 47481-E, 52318-E to 52320-E, incl., 55422-E, 55604-E, 58291-E, 79926-E.)

Between December 28, 1940, and September 17, 1941, the United States attorneys for the Eastern District of Missouri, Western District of Washington, Northern District of California, District of Oregon, Southern District of Ohio, Western District of Louisiana, Northern District of Oklahoma, Eastern District of Wisconsin, Southern District of Indiana, and the District of Minnesota filed libels against 91¼ dozen boxes of Slend-R-Form at St. Louis, Mo., 451 boxes at Seattle Wash., 140 boxes at San Francisco, Calif., 19 dozen boxes at Portland, Oreg., 140 boxes at Dayton, Ohio, 25 boxes at Appleton, Wis., 54 boxes at Lake Charles, La., 24 boxes at Tulsa, Okla., 126 boxes at Milwaukee, Wis., 16 boxes at Indianapolis, Ind., and 274 packages at Minneapolis, Minn., alleging that the article had been shipped in interstate commerce within the period from on or about October 28, 1940, to on or about August 7, 1941, by Riley Products, Inc., from Chicago, Ill. On March 10, 1941 the United States attorney for the District of Colorado filed a libel against 8 dozen boxes of Slend-R-Form Candy at Denver, Colo., which had been shipped by Riley Products, Inc., from Chicago, Ill., on or about December 3, 1940.

The article was alleged to be misbranded in that representations in the labeling regarding its efficacy in effecting a reduction of body weight in the consumer were false and misleading. The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2978.

Between January 30, 1941, and March 4, 1942, no claimant having appeared, judgments of condemnation were entered. The portions of the product located at Denver, Dayton, and Minneapolis were ordered distributed to charitable institutions and the remaining lots were ordered destroyed.

595. Misbranding of Slend-R-Form. U. S. v. 58 Boxes of Slend-R-Form. Default decree of condemnation and destruction. (F. D. C. No. 4290. Sample Nos. 24696-E, 37283-E.)

On April 17, 1941, the United States attorney for the Northern District of Illinois filed a libel against 58 boxes of Slend-R-Form candy at Chicago, Ill., alleging that the article had been shipped in interstate commerce on or about April 2, 1941, by Thomas Martindale & Co. from Philadelphia, Pa.; and charging that it was misbranded. This was a returned shipment and was part of a lot originally shipped to Philadelphia by Riley Products, Inc., from Chicago, Ill.

The article was alleged to be misbranded in that representations in the labeling regarding its efficacy in effecting reduction of body weight in the consumer were false and misleading.

The article was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2977.

On June 30, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

596. Misbranding of Pro-Gro Poultry Supplement. U. S. v. 3 10-Pound, 3 25-Pound, and 1 335-Pound Containers of Pro-Gro. Consent decree of condemnation and destruction. (F. D. C. Nos. 4379, 4380. Sample Nos. 43876–E, 43877–E.)

On April 21, 1941, the United States attorney for the District of Kansas filed a libel against the above-named product at Ottawa, Kans., alleging that it had been shipped by the Pro-Gro Co. from Kansas City, Mo., on or about January 28, 1941; and charging that it was misbranded. With the exception of the portion contained in one of the 10-pound containers, the article was unlabeled.

Analyses of samples of the product showed that it consisted essentially of cut plant material containing minute proportions of hydrochloric and sulfuric acids.

The labeled portion of the article was alleged to be misbranded in that the statements, "Pro—Produces More Eggs! Gro Grows More Meat! Poultry Supplement Fertility . . . Vitality," were false and misleading since they represented that it would be efficacious for the purposes recommended, whereas it would not be efficacious for such purposes; and in that the name "Pro-Gro," a combination of letters, was a false and misleading device which was interpreted to mean that the article would produce more eggs and grow more meat. Both the labeled and the unlabeled portions were alleged to be misbranded in that the article was in package form and the label failed to bear (1) a statement of the common or usual names of the active ingredients, and (2) an accurate statement of the quantity of contents. The portion in the unlabeled containers was alleged to be misbranded further in that it was in package form and did not bear a label containing the name and place of business of the manufacturer, packer, or distributor.

It also was alleged to be misbranded under the provisions of the law applicable to foods, as reported in F. N. J. No. 2858.

On June 21, 1941, the claimant having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered destroyed.

597. Misbranding of Udder-Balm. U. S. v. 7½ Cases of Udder-Balm. Default decree of condemnation and destruction. (F. D. C. No. 3683. Sample No. 55386–E.)

On January 23, 1941, the United States attorney for the Western District of Washington filed a libel against the above-named product at Seattle, Wash., alleging that the article had been shipped in interstate commerce on or about June 15, 1939, by Cash Davis Laboratories from St. Helens, Oreg.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of free iodine, combined iodine, petrolatum, and a fatty acid.

The article was alleged to be misbranded in that representations in the labeling that it would be efficacious for the treatment of mastitis and cowpox were false and misleading since it would not be efficacious for such purposes.

On June 17, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

598. Misbranding of worm remedies for poultry and hogs. U. S. v. 25 Packages of Kon-Trold Kamala Flock Treatment for Poultry, 17 Packages of Kon-Trold Nicotine for Poultry Round Worms, and 29 Packages of Kon-Trold Nicotine Herd Treatment for Hog Round Worms. Default decree of condemnation and destruction. (F. D. C. Nos. 4239 to 4241, incl. Sample Nos. 60046–E to 60048–E, incl.)

On April 10, 1941, the United States attorney for the District of Oregon filed a libel against the above-named products at Eugene, Oreg., alleging that they had been shipped by Kon-Trold Products Corporation from Burbank, Calif., on or about July 16, 1940; and charging that they were misbranded.

Analyses of samples of the articles showed that the Kamala Flock Treatment for Poultry consisted essentially of kamala resins and siliceous material; that the Nicotine for Poultry Round Worms consisted essentially of nicotine and rosin; and that the Nicotine Herd Treatment consisted essentially of nicotine and rosin.

The articles were alleged to be misbranded in that statements in the labeling representing that the Flock Treatment for Poultry would be efficacious in the treatment of poultry afflicted with tapeworms; that the Nicotine for Poultry Round Worms would be efficacious for treatment and prevention of roundworms in poultry; and that the Herd Treatment for Hog Round Worms would be efficacious for treatment of hog roundworms and beneficial at any time to hogs of all ages, were false and misleading since they would not be efficacious for such purposes.

The Nicotine for Poultry Round Worms was alleged to be misbranded further in that the statement of active ingredients, which appeared in type of a very small size, was not placed on the label with such conspicuousness as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

On May 9, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

DRUGS FALSELY LABELED AS TO QUANTITY OF CONTENTS[4]

599. Alleged misbranding of rubbing alcohol compound. U. S. v. Adde, Inc. Plea of not guilty. Case tried to the court sitting as a jury of one; verdict of not guilty. (F. D. C. No. 2092. Sample Nos. 321–E, 322–E, 13026–E, 13027–E, 64236–E.)

This case was instituted on charges that the product was short of the declared volume.

On August 1, 1940, the United States attorney for the District of Maryland filed an information against Adde, Inc., a corporation, Baltimore, Md., alleging shipment on or about November 1 and 29 and December 26 and 27, 1939, from the State of Maryland into the States of North Carolina and Washington of quantities of rubbing alcohol compound that was misbranded.

The article was alleged to be misbranded in that the following statements on the carton and bottle labels, "Contents One Pint," "Contents 16 Fl. Ozs.," and "Contents 16 Fluid Ozs.," were false and misleading since each of the bottles did not contain 1 pint or 16 fluid ounces of rubbing alcohol, but did contain a smaller amount.

On October 20, 1941, a plea of not guilty was entered on behalf of the defendant and the case was tried before the court sitting as a jury of one. At the conclusion of testimony the court ordered the entry of a verdict of not guilty and delivered the following oral opinion:

COLEMAN, *District Judge.* "The court, sitting as a jury, concludes that the defendant company is entitled to a directed verdict in its favor, for the following reasons:

"The defendant company is charged with violating Section 502 (b) (2) of the Act of June 25, 1938, 21 U. S. C. A. Sec. 352 (b) (2), known as the Federal Food, Drug and Cosmetic Act, which provides that 'A drug or device shall be deemed to be misbranded—(b) if in package form unless it bears a label containing * * * (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by law.'

"Regulations have been prescribed under this section of the act and they have the force of law, provided they are consistent with the statute. In other words, rules promulgated by an administrative body in support of the legislation which it is charged with enforcing, are always subject to judicial review. In the present case the regulation here relied upon by the Government, namely, subdivision (j) of the regulations prescribed by the Secretary pursuant to section 502 of the act, is found by the court to be a reasonable and proper regulation. It reads as follows, insofar as its provisions relate to the present inquiry: 'Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure of a drug caused by ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably

[4] See also Nos. 546, 551, 554–556, 571, 582, 583, 596.

result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large. * * *.'

"All of the bottles involved in the present suit contain as part of their label the words "Contents 16 fluid ounces," which this court believes must be construed as expressing a minimum quantity. So the above-quoted regulation applies.

"It is contended on the part of the Government that subsection (k) of this same section of the regulations also applies. That reads as follows: 'Where the statement does not express the minimum quantity—

"'(1) variations from the stated weight or measure of a drug shall be permitted when caused by ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

"'(2) variations from the stated weight, measure, or numerical count of a drug or device shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting the contents of individual packages which occur in good packing practices.

"'But under subdivision (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the drug or device is below the quantity stated and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.'

"Even if we assume this last quoted regulation to be applicable to the present case, the testimony introduced clearly fails to establish that 'the average of the quantities in the packages comprising a shipment' is 'below the quantity stated.' The Government has not introduced any testimony sufficiently extensive to support that contention.

"The following regulation (1), prescribed under section 502, is also applicable to the present case: 'The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this regulation in the case of each shipment or other delivery shall be determined by the facts in such case.'

"When we apply the rule laid down in regulations (j) and (l) just referred to, the court is completely satisfied that the Government has failed to sustain the burden, imposed upon it in a case of this kind, of proving beyond a reasonable doubt that the defendant company is guilty of violating the act.

"It is true that proof of intent on the part of an alleged offender to do the forbidden act is not a condition precedent. The act prohibits doing certain things, and if the Government proves that they have been done then the person or firm shown to have been guilty of the violation, is liable under the act for the penalties imposed, regardless of intent. However, it seems to the court in the present case that the Government is taking what is, in substance, a contradictory position. First, it says that it believes the variation or deficiency in the weights of the samples taken is a clear violation of the law, as interpreted by the regulations which have just been referred to. and yet, at the same time, the Government admits that following these alleged violations, the loading facilities of the defendant company were never inspected, but that the Government accepted statements made by State of Maryland inspectors that such facilities were adequate and satisfactory. And what is more important, the record in the present case is totally devoid of any testimony tending to show what might be the shrinkage or evaporation in samples taken promptly after the bottles are loaded, and laid aside for a period of time approximating the time that elapsed between the shipment and the examination of the bottles that were actually sampled. This lack of testimony seems to the court to be very vital.

"It is clear that under some conditions, merely through evaporation greater shrinkages than those with respect to which Government witnesses have testified, occur in alcohol preparations of this character. This is proved by the analysis, made in the course of this trial at the court's request, of the contents of one of the bottles taken from one of the very shipments from which the Government took samples and made its measurements.

"The Government has not itself arrived at a standard by percentages which it is prepared to adopt. It simply says that the shrinkage here is on the average too great, after sampling some 70-odd samples out of many hundreds of bottles. There is no proof but what the deficiency complained of may just as well have been caused by the very sort of thing which the regulations allow to be taken into

account, namely, 'ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure,' as by short loading.

"To repeat, it seems to the court that if the Government desires to prosecute defendants in a case of this kind, it should support its case with more accurate data. The court realizes that it is not possible to lay down a rule of thumb requirement. There is bound to be some tolerance. In the present case the Government asserts that a proven shrinkage in the samples taken in the neighborhood of 1 ounce for every 16 ounces, which is the minimum quantity each bottle is labeled to contain, is an excessive shrinkage. Yet, as has just been noted, the measurement in open court indicates that perhaps such a shrinkage is due 'to ordinary and customary exposure.' There is no testimony in the present case as to what the actual extent of the evaporation of alcohol, or water, or both, would be over a given period of time in a preparation of this kind, under stated temperature conditions. Perhaps any such tests would produce variations which would not enable one to adopt a percentage rule, in any event. But the sum and substance of this court's conclusion is that the Government can not properly rely solely upon samples taken long after the shipments had been made, under variable temperature conditions, which do not represent an average of anything like an entire shipment, or shipment, especially since the Government has given to this defendant a clean bill of health as to its present loading facilities, without having its own representatives inspect such facilities and determine, and be prepared to prove that there has been short loading.

"At first blush it would seem that if a man says to the public, by the label on his bottle, that he has put 16 ounces of his preparation in that bottle when as a matter of fact when the bottle reaches the consumer there are only 15 or 14½ ounces in it, there is something wrong. But in the present case the evidence shows that a considerable portion of the liquid is highly volatile, being alcohol. It also shows that the Government has failed to determine by direct evidence whether the shortage actually occurred in the loading or by evaporation. It merely draws the conclusion from a relatively small number of samples that this shortage could not have occurred except in the loading. If the Government had investigated defendant's loading methods, and had immediately laid aside a number of the loaded bottles under conditions similar to the conditions which existed with respect to the samples that were tested, it could then be determined with accuracy whether there was shrinkage after loading, and to what extent, if any, there was short loading.

"What the court has said is not to be taken as meaning that one who prepares and sells a volatile preparation is not himself required to take that characteristic into account in bottling his preparation. Of course he is. But he is given the benefit of the tolerance rule contained in the regulations just referred to. And since this is a criminal case, and the burden of proof is upon the Government to establish to the satisfaction of the court sitting as a jury beyond a reasonable doubt that the law has been violated, that rule must be given full force and effect also.

"The verdict is accordingly not guilty."

600. Misbranding of Essence of Caroid. U. S. v. 10 Bottles of Essence of Caroid. Default decree of condemnation. Product ordered delivered to Food and Drug Administration for technical use. (F. D. C. No. 6258. Sample No. 87104-E.)

On November 21, 1941, the United States attorney for the District of Columbia filed a libel against 10 1-gallon cartons of Essence of Caroid at Washington, D. C., alleging that the article had been shipped by the American Ferment Co., Inc., from Buffalo, N. Y., on or about October 21, 1941; and charging that it was misbranded.

The article was alleged to be misbranded (1) in that the statement on the label, "1 Gal.," was false and misleading since the quantity of contents of the package was materially less than 1 gallon; and (2) in that the label failed to bear an accurate statement of the quantity of contents.

On December 22, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to the Food and Drug Administration for technical use.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 541–600

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] Contains an opinion of the court.

U. S. GOVERNMENT PRINTING OFFICE: 1942